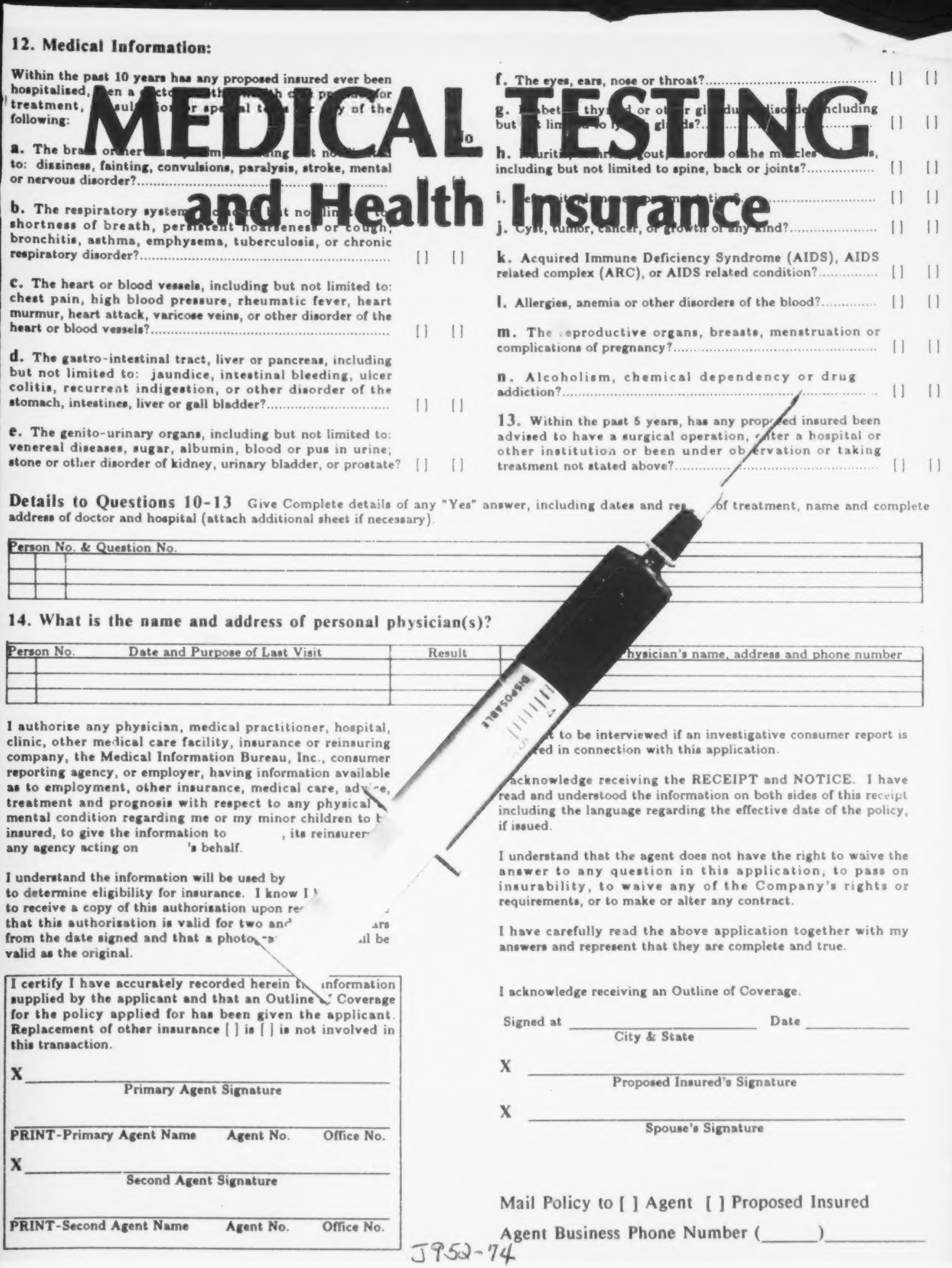
# MEDICAL TESTING and Health Insurance



**12. Medical Information:**

Within the past 10 years has any proposed insured ever been hospitalised, [illegible] treatment, [illegible] following:

a. The bra[illegible] to: dizziness, fainting, convulsions, paralysis, stroke, mental or nervous disorder?................ [ ] [ ]

b. The respiratory system [illegible] shortness of breath, persistent hoarseness or cough, bronchitis, asthma, emphysema, tuberculosis, or chronic respiratory disorder?................ [ ] [ ]

c. The heart or blood vessels, including but not limited to: chest pain, high blood pressure, rheumatic fever, heart murmur, heart attack, varicose veins, or other disorder of the heart or blood vessels?................ [ ] [ ]

d. The gastro-intestinal tract, liver or pancreas, including but not limited to: jaundice, intestinal bleeding, ulcer colitis, recurrent indigestion, or other disorder of the stomach, intestines, liver or gall bladder?................ [ ] [ ]

e. The genito-urinary organs, including but not limited to: venereal diseases, sugar, albumin, blood or pus in urine; stone or other disorder of kidney, urinary bladder, or prostate? [ ] [ ]

f. The eyes, ears, nose or throat?................ [ ] [ ]

g. [illegible] thy[illegible] or ot[illegible] including but [illegible] gl[illegible]ds?................ [ ] [ ]

h. [illegible] gout [illegible] of the m[illegible] including but not limited to spine, back or joints?................ [ ] [ ]

i. [illegible]................ [ ] [ ]

j. Cyst, tumor, cancer, or growth of any kind?................ [ ] [ ]

k. Acquired Immune Deficiency Syndrome (AIDS), AIDS related complex (ARC), or AIDS related condition?................ [ ] [ ]

l. Allergies, anemia or other disorders of the blood?................ [ ] [ ]

m. The reproductive organs, breasts, menstruation or complications of pregnancy?................ [ ] [ ]

n. Alcoholism, chemical dependency or drug addiction?................ [ ] [ ]

13. Within the past 5 years, has any proposed insured been advised to have a surgical operation, enter a hospital or other institution or been under observation or taking treatment not stated above?................ [ ] [ ]

**Details to Questions 10-13** Give Complete details of any "Yes" answer, including dates and re[illegible] of treatment, name and complete address of doctor and hospital (attach additional sheet if necessary).

| Person No. & Question No. | | |
|---|---|---|
| | | |
| | | |
| | | |

**14. What is the name and address of personal physician(s)?**

| Person No. | Date and Purpose of Last Visit | Result | [illegible]hysician's name, address and phone number |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

I authorize any physician, medical practitioner, hospital, clinic, other medical care facility, insurance or reinsuring company, the Medical Information Bureau, Inc., consumer reporting agency, or employer, having information available as to employment, other insurance, medical care, advice, treatment and prognosis with respect to any physical [illegible] mental condition regarding me or my minor children to b[illegible] insured, to give the information to , its reinsurer[illegible] any agency acting on 's behalf.

I understand the information will be used by to determine eligibility for insurance. I know I [illegible] to receive a copy of this authorisation upon re[illegible] that this authorisation is valid for two and [illegible] from the date signed and that a photo[illegible] [illegible] valid as the original.

[illegible] to be interviewed if an investigative consumer report is [illegible]ed in connection with this application.

[illegible]acknowledge receiving the RECEIPT and NOTICE. I have read and understood the information on both sides of this receipt including the language regarding the effective date of the policy, if issued.

I understand that the agent does not have the right to waive the answer to any question in this application, to pass on insurability, to waive any of the Company's rights or requirements, or to make or alter any contract.

I have carefully read the above application together with my answers and represent that they are complete and true.

I certify I have accurately recorded herein th[illegible] information supplied by the applicant and that an Outline [illegible] Coverage for the policy applied for has been given the applicant. Replacement of other insurance [ ] is [ ] is not involved in this transaction.

X ______________________
Primary Agent Signature

PRINT-Primary Agent Name Agent No. Office No.

X ______________________
Second Agent Signature

PRINT-Second Agent Name Agent No. Office No.

I acknowledge receiving an Outline of Coverage.

Signed at ______________ Date __________
City & State

X ______________________
Proposed Insured's Signature

X ______________________
Spouse's Signature

Mail Policy to [ ] Agent [ ] Proposed Insured

Agent Business Phone Number (_____)__________

J952-74

CONGRESS OF THE UNITED STATES OFFICE OF TECHNOLOGY ASSESSMENT

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**The Technology Assessment Board approves the release of this report. The views expressed in this report are not necessarily those of the Board, OTA Advisory Council, or individual members thereof.**

# MEDICAL TESTING
## and Health Insurance

CONGRESS OF THE UNITED STATES OFFICE OF TECHNOLOGY ASSESSMENT

Recommended Citation:

U.S. Congress, Office of Technology Assessment, *Medical Testing and Health Insurance*, OTA-H-384 (Washington, DC: U.S. Government Printing Office, August 1988).

Library of Congress Catalog Card Number 88-600536

For sale by the Superintendent of Documents
U.S. Government Printing Office, Washington, DC 20402-9325
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# Foreword

Tests to identify individuals who are likely to develop serious diseases are being rapidly developed. Some of these tests are directed at diseases for which there are presently no known therapies, thereby raising questions over the social consequences of identifying susceptible persons. Other tests are directed at diseases that are among the foremost causes of morbidity and mortality, such as cardiovascular diseases and cancer, but for which clear-cut relationships between test positivity and a high probability of developing disease have yet to be established. Available tests for identifying persons infected with the AIDS virus are very accurate, but whom to test is a highly controversial issue because of the social consequences of being identified as a carrier of the AIDS virus.

The health status and risk of developing disease of individuals applying for health insurance are routinely evaluated by private health insurers, and applicants may be declined altogether, charged higher premiums, or have certain illnesses excluded from coverage. Medical testing may be included in evaluating the applicant, so wider use of diagnostic and predictive medical tests by insurers is a real possibility as such tests are improved and more tests become available. Many employers—especially large employers—are also foregoing the use of traditional insurers and are self-insuring the health care costs of their employees, so they may have similar incentives to use medical tests when hiring prospective employees.

Such uses of medical tests may lead to substantial costs to government if private insurance becomes too costly or unavailable to selected individuals. Furthermore, approximately 15 percent of the population of the United States do not have health insurance, and an additional 8 to 26 percent of the population under age 65 are underinsured. Thus, use of medical tests in determining insurability and employability not only affects the balance between governmental and private sector financing of health care, but also can aggravate the problem of the uninsured and underinsured.

This assessment examines existing and developing medical tests and their current and potential uses by health insurers and employers. Two related reports have previously been issued as part of this study. *AIDS and Health Insurance: An OTA Survey* was issued in February 1988 and examined health insurance underwriting practices and AIDS claims experience for individually underwritten insurance policies. *The Impact of AIDS on the Kaiser Permanente Medical Care Program (Northern California Region)* was released in July 1988.

OTA was ably assisted in this study by an advisory panel, chaired by Irving Lewis, Emeritus Professor of Public Policy and Community Health at the Albert Einstein College of Medicine. Many individuals and organizations with expertise and interest in these areas also provided information and reviewed a draft of the report. The final responsibility for the content of this assessment rests with OTA. Key staff involved in the analysis and writing were Larry Miike, Jill Eden, Maria Hewitt, Laurie Mount, and Ellen Smith.

John H Gibbons

JOHN H. GIBBONS
*Director*

# Medical Testing and Health Insurance Advisory Panel

Irving Lewis, *Chairman*
Emeritus Professor of Public Policy and Community Health
Albert Einstein College of Medicine
Bronx, New York

Donald Chambers
Chief Medical Director
Lincoln National Life Insurance Co.
Ft. Wayne, Indiana

Rashi Fein
Professor of the Economics of Medicine
Harvard Medical School
Boston, Massachusetts

Peter Groom
Senior Counsel
Department of Insurance
State of California
San Francisco, California

William Hagar[1]
Insurance Commissioner,
Iowa Division of Insurance
Des Moines, Iowa

Robert Hunter
President
National Insurance Consumer Organization
Alexandria, Virginia

Angele Khachadour
General Counsel
Blue Cross of California
Oakland, California

Barbara Matula
Director
Division of Medicaid Assistance
State of North Carolina
Raleigh, North Carolina

Saul Milles
Associate Company Medical Director
General Electric Co.
Fairfield, Connecticut

Lee Moskowitz
Director
Immunopathology and Serology Laboratory
Cedars Medical Center
Miami, Florida

Nanette Newell
The Synertech Group Inc.
Research Triangle Park, North Carolina

Mark Pauly
Executive Director
Leonard Davis Institute of Health Economics
Wharton School
University of Pennsylvania
Philadelphia, Pennsylvania

Gordon Polley
President
Molecular Diagnostics, Inc.
West Haven, Connecticut

Mark Rothstein
Director
Health Law Institute
University of Houston Law Center
Houston, Texas

Tom Stoddard
Executive Director
LAMBDA Legal Defense and Education Fund
New York, New York

Deborah Stone
David Pokross Professor of Law and Social Policy
Heller School
Brandeis University
Waltham, Massachusetts

Robert Swanke
President
Swanke, Inc.
Bloomington, Minnesota

Paul Volberding
Chief, Medical Oncology Division and AIDS Activities Division
UCSF/SF General Hospital
San Francisco, California

Susan Walker[2]
Director
South Dakota Lottery[3]
State Capitol Building
Pierre, South Dakota

Harry Woodman, Jr.
Vice President
New York Life Insurance Co.
New York, New York

---

[1] From October 1987.
[2] Until October 1987.
[3] Former Director of Insurance, State of South Dakota.

NOTE: OTA gratefully acknowledges the members of this advisory panel for their valuable assistance and thoughtful advice. The panel does not, however, necessarily approve, disapprove, or endorse this report. OTA assumes full responsibility for the report and the accuracy of it contents.

# OTA Project Staff—Medical Testing and Health Insurance

Roger C. Herdman, *Assistant Director, OTA*
*Health and Life Sciences Division*

Clyde J. Behney, *Health Program Manager*

## Project Staff

**Lawrence H. Miike,** *Project Director*

Jill S. Eden, *Analyst*

Maria Hewitt, *Analyst*

Laurie Mount, *Research Analyst*

Ellen Smith, *Analyst**

## Administrative Staff

Virginia H. Cwalina, *Administrative Assistant*

Carol Ann Guntow, *P.C. Specialist*

Karen T. Davis, *Secretary/Word Processor Specialist*

Carolyn D. Martin, *Clerical Assistant*

## Contractors

Glenn Markus, *Health Policy Alternatives, Inc.*

Katherine Swartz, *The Urban Institute*

Kaiser Permanente Medical Care Program (Northern California Region)

---

*Until September 1987.

## List of Abbreviations

ACLI —American Council on Life Insurance
ACLU —American Civil Liberties Union
ACS —American Cancer Society
AIDS —acquired immunodeficiency syndrome
ALT —alanine amino transferase (formerly SGPT)
AMA —American Medical Association
APS —attending physician's statement
ARC —AIDS-related complex
ASO —administrative services only
AST —aspartate amino transferase (formerly SGOT)
BC/BS —Blue Cross/Blue Shield
BLS —Bureau of Labor Statistics
BUN —blood urea nitrogen
CAD —coronary artery disease
CAP —College of American Pathologists
CDC —Centers for Disease Control
CEA —carcinoembryonic antigen
CFR —Code of Federal Regulations
CHD —coronary heart disease
CHIPs —catastrophic health insurance plans
CMPs —competitive medical plans
COBRA —Consolidated Omnibus Budget Reconciliation Act of 1985
CPS —Current Population Survey
CSO —claims services only
DHHS —U.S. Department of Health and Human Services
DNA —deoxyribonucleic acid
DOD —U.S. Department of Defense
DOT —U.S. Department of Transportation
EIA —enzyme immunoassay
EKG —Electrocardiogram
ELISA —enzyme-linked immunosorbent assay
ERISA —Employee Retirement and Income Security Act
ESRD —end-stage renal disease
FDA —U.S. Food and Drug Administration
FH —familial hypercholesterolemia
GAO —U.S. General Accounting Office
GC/MS —gas chromatography/mass spectrometry
GGT —gamma-glutamyl transpeptidase
GHAA —Group Health Association of America
HCFA —Health Care Financing Administration
HDL —high density lipoproteins
HIAA —Health Insurance Association of America
HIS —Health Interview Survey
HIV —Human Immunodeficiency Virus
HMO —health maintenance organization
HORL —Home Office Reference Laboratory, Inc.
HRA —health risk appraisals
IFA —indirect immunofluorescence assay
LDL —low density lipoproteins
METs —multiple employer trusts
MI —myocardial infarction
MIB —Medical Information Bureau, Inc.
MRI —magnetic resonance imaging (formerly NMR)
NAHMOR—National Association of HMO Regulators
NAIC —National Association of Insurance Commissioners
NIDA —National Institute on Drug Abuse
NIH —National Institutes of Health
NIOSH —National Institute for Occupational Safety and Health
NMCES —National Medical Care Expenditure Survey
NMCUES —National Medical Care Utilization and Expenditure Survey
NMR —nuclear magnetic resonance (former name for MRI)
ODPHP —U.S. Office of Disease Prevention and Health Promotion (PHS)
OPM —U.S. Office of Personnel Management
OTA —Office of Technology Assessment (U.S. Congress)
OTC —over-the-counter
PHS —U.S. Public Health Service
PMA —premarket approval
PPO —preferred provider organization
RBC —red blood cell
RFLPs —restriction fragment length polymorphisms
RIPA —radioimmunoprecipitation assay
RNA —ribonucleic acid
SIPP —Survey of Income and Program Participation
SGOT —serum glutamic-oxaloacetic transaminase (former name for AST)
SGPT —serum glutamic pyruvic transaminase (former name for ALT)
STD —sexually transmitted disease
TPAs —third party administrators
VLDL —very low density lipoproteins
WBC —white blood cell

## Glossary of Terms

**Accuracy ("diagnostic accuracy"):** In describing a diagnostic test, diagnostic accuracy is the number of correct test results (i.e., the total of true-positives and true-negatives) divided by the total number of tests performed. Diagnostic accuracy may vary with the prevalence of the disease in the population. See also *sensitivity* and *specificity*.

**Acquired immunodeficiency syndrome:** The most severe clinical manifestation of immune dysfunction caused by the human immunodeficiency virus (HIV).

**Adverse selection:** The tendency of persons with poorer than average health expectations to apply for or continue insurance to a greater extent than persons with average or better health expectations. Also known as "antiselection."

**Allele:** An alternative form of a gene, or a group of functionally-related genes, located at the corresponding site on the chromosome. Alleles are inherited separately from each parent, and can be dominant, recessive, or co-dominant for a particular trait.

**Antibody:** A blood protein (immunoglobulin) produced by white blood cells in response to the introduction of a specific antigen (usually a protein). Once produced, the antibody has the ability to combine with the specific antigen that stimulated antibody production. This reaction to foreign substances is part of the immune response. At present, five classes of antibodies are distinguishable. Most of the circulating antibodies are immunoglobulin G (IgG); the others are IgM, IgA, IgD, and IgE. See also *immunoglobulin*.

**Antigen:** A substance, usually a protein or complex carbohydrate, which, when introduced into the body of a human or other animal, stimulates the production of an antibody that reacts specifically with it.

**Autoradiograph:** An image produced on an x-ray film by a radioactively labeled substance.

**Biochemical profile:** A battery of twelve or more biochemical blood tests (e.g., calcium, glucose, blood urea nitrogen, total protein) that is conducted using large-volume, automated instruments. Biochemical profiles are sometimes used to screen asymptomatic adults in an effort to identify those with latent disease or those at high risk of developing chronic disease.

**Cholesterol:** An alcohol found in egg yolks, oils, and fats. Cholesterol is used to synthesize cell membranes, is a precursor to steroid hormones, and is a component of bile.

**Chromosome:** A rod-like structure found in the cell nucleus and containing the genes. Chromosomes are composed of DNA and proteins. They can be seen in the light microscope during certain stages of cell division.

**Coinsurance:** A provision in a health insurance contract by which the insurer and insured share, in a specific ratio, the covered losses under a policy. For example, the insurer may reimburse the insured for 80 percent of covered expenses, the insured paying the remaining 20 percent of such expenses.

**Community-rating:** A method of determining premium rates that is based on the allocation of total costs without regard to past group experience. Community rating is required of federally qualified HMOs.

**Conversion privilege:** The right to change insurance without providing evidence of insurability, usually to an individual policy upon termination of coverage under a group contract. Conversion privileges are mandated by the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Public Law 99-272).

**Core antigens:** Antigens that make up the internal structure or core of a virus. Compare *envelope antigens*.

**Deductible:** The amount of covered expenses that must be incurred and paid by the insured before benefits become payable by the insurer.

**Deoxyribonucleic acid (DNA):** The substance of heredity; a large molecule which carries the genetic information necessary for the replication of cells and for the production of proteins. DNA is composed of the sugar deoxyribose, phosphate, and the bases adenine, thymine, guanine, and cytosine.

**DNA denaturation:** The separation of DNA into its two strands of nucleotides, for example by exposing it to near-boiling temperatures or to extremely alkaline conditions.

**DNA probe:** A specific sequence of single-stranded DNA used to seek out a complementary sequence in other single strands. The probe is usually made radioactive so that it can be detected.

**DNA sequencing:** The process of determining the nucleotide sequences of DNA.

**Diagnostic test:** A medical test administered to those asymptomatic but high risk individuals identified by a screening test or a test used to identify the cause of abnormal physical signs or symptoms. Compare *predictive test* and *screening test*.

**Direct genetic test:** A DNA-based test capable of identifying a specific disease-causing allele. Compare *linkage test*.

**Direct pay:** See *individual health insurance*.

**Electrophoresis:** A method of separating substances, such as DNA fragments, by using an electric field to make them move through a medium at rates that correspond to their electric charge and size.

**Electrocardiogram (EKG or ECG):** A graphic tracing of the changes of electrical potential of the heart occurring during each heartbeat; usually performed with the patient supine and at rest.

**Envelope antigens:** Proteins that comprise the envelope or surface of a virus. Compare *core antigens*.

**Enzyme immunoassay (EIA):** An assay based on antigen-antibody interactions, which uses enzymes to measure the reaction. For example, in EIAs that are used to measure drugs in urine, a reagent that contains antibodies against a specific drug is first added to the urine specimen. A second reagent containing the specific drug attached to an enzyme is then added, and the enzyme-labeled drug combines with any remaining antibody binding sites. This binding decreases the enzyme activity. The residual enzyme activity relates directly to the concentration of drug in the specimen. The active enzyme converts another substance in the reagent, resulting in an absorbance change that is measured spectrophotometrically. See also *indirect immunofluorescence assay* and *radioimmunoprecipitation assay*.

**Enzyme-linked immunosorbent assay (ELISA):** A type of enzyme immunoassay; for example, an ELISA is used to test for the presence of antibodies to HIV.

**Exclusion waiver:** An agreement attached to an insurance policy which eliminates a specified preexisting condition from coverage under the policy.

**Experience-rating:** A method of determining group premium rates based on the actual amount of claim payments made on behalf of the group in a prior period, usually the preceding year.

**False negative:** A negative test result in an indiviudal who actually has the disease or characteristic being tested for. The patient is incorrectly diagnosed as not having a particular disease or characteristic.

**False positive:** A positive test result in an individual who does not have the disease or characteristic being tested for. The individual is incorrectly diagnosed as having a particular disease or characteristic.

**Familial hypercholesterolemia (FH):** An autosomal dominant disease caused by inherited defects in the gene encoding for the low density lipoprotein receptor. The defects disrupt the normal control of cholesterol metabolism.

**Federally qualified HMO:** An HMO that is certified as meeting the qualification requirements of the Federal Health Maintenance Act of 1973, as amended (42 U.S.C. Sec. 300e et seq.). Federally qualified HMOs must adhere to certain financial, underwriting, and rate-setting standards and provide specified, medically necessary health services.

**Gas chromatography/mass spectrometry (GC/MS):** A method of identifying specific substances (for example, drugs), in which a gas chromatograph is coupled with a mass spectrometer. The gas chromatograph is used to separate individual substances by the rate they traverse the chromatograph column. As these compounds exit the chromatographic column, they may, for example, be bombarded with electrons, with each substance breaking up into characteristic pieces that can be identified with the mass spectrometer. A GC/MS can be calibrated to scan for many substances in a specimen, or to monitor for only a few masses that are characteristic of a particular substance.

**Gene:** A unit of heredity; a segment of the DNA molecule containing the code for a specific function.

**Gene expression:** The manifestation of the genetic material of an organism as specific traits. Specific gene products are expressed as proteins.

**Genetics:** The scientific study of heredity: how particular qualities or traits are transmitted from parents to offspring.

**Genome:** The total genetic endowment packaged in the chromosomes. The normal human genome consists of 46 chromosomes.

**Human Immunodeficiency Virus (HIV):** A retrovirus that is the etiologic agent of AIDS.

**Huntington's disease:** A disease that generally appears in adulthood, producing progressive mental and physical deterioration; it is caused by a dominant gene.

**Hybridization:** The placement of complementary single strands of nucleic acids together so that they will stick and form a double strand. The technique of hybridization is used in conjunction with probes to detect the presence or absence of specific complementary nucleic acid sequences.

**In situ hybridization:** A method to identify HIV-produced RNA or DNA which involves the use of radioactive-labeled probes.

**Immunoglobulin:** Any of the serum proteins with antibody activity. See also *antibody*.

**Incidence:** The number of new cases of a disease in a population over a specified period of time. Compare *prevalence*.

**Indirect immunofluorescence assay (IFA):** An assay based on antigen-antibody interactions. For example, in searching for viral antigens (such as HIV) in cells, antibodies to the specific viral antigen are first added. Fluorescein-labeled goat antihuman globulin is then added, which binds to antibodies attached to the viral antigen, and these viral antigens are then detailed with a fluorescent microscope. See also *enzyme immunoassay* and *radioimmunoprecipitation assay*.

**Individual health insurance:** Health insurance that covers an individual and often members of his or her family without any association with an employer or membership group of any kind.

**Individually underwritten groups:** Small employee groups that usually include no more than 50 individuals. Small group underwriting requires that individual group members provide a statement of health and evidence of insurability.

**Linkage:** The relationship between two genes, or between an identifiable trait and a genetic disorder. Genes that are located relatively close to each other on the same chromosome are said to be linked and generally are inherited together.

**Lipoprotein:** Compounds consisting of lipids (fatty substances such as cholesterol) and proteins. Lipoproteins are classified as very low-density (VLD), low-density (LD), and high-density (HD).

**Locus:** The site of a gene on a chromosome.

**Lymphocyte:** A white blood cell which is part of the immune system.

**Magnetic resonance imaging (MRI):** A technique that produces images of the body by measuring the reaction of nuclei (typically of hydrogen protons) in magnetic fields to radiofrequency waves. Formerly known as nuclear magnetic resonance (NMR).

**Monoclonal antibodies (MAbs):** Antibodies derived from a single source or clone of cells. MAbs recognize only one type of antigen.

**Multiple employer trusts (METs):** A method of insurance in which small employers band together and act as a large employer to create a larger risk pool so that premiums can be lower compared to premiums based on each employer's smaller risk pool.

**Myocardial infarction (MI):** Necrosis (death) of tissue in the myocardium (heart muscle) that results from insufficient blood supply to the heart.

**Nuclear magnetic resonance:** See *magnetic resonance imaging (MRI)*.

**Nucleic acids:** DNA and RNA, the molecules that carry genetic information.

**Nucleotide:** A building block of DNA or RNA. It includes one base, one phosphate molecule, and one sugar molecule (deoxyribose in DNA, ribose in RNA).

**Oligonucleotide:** A short string of nucleotides.

**Oligonucleotide probe:** A short DNA sequence which is synthesized from a known gene or segment of a gene that can be either normal or mutant.

**Oncogene:** A gene of which one or more mutant forms is associated with cancer formation.

**Oncolipid:** Alterations of the lipid moieties of lipoprotein particles found in the plasma of patients with cancer.

**Open enrollment:** A health insurance enrollment period during which coverage is offered regardless of health status and without medical screening. Open enrollment periods are characteristic of some BC/BS plans and HMOs.

**Penetrance:** A term used to refer to the frequency with which the effects of a gene (whether dominant or recessive) known to be present are actually seen in the individuals carrying it.

**Phenylketonuria (PKU):** An autosomal recessive genetic disorder of amino acid metabolism, caused by the inability to metabolize phenylalanine to tyrosine. The resulting accumulation of phenylalanine and derived products causes mental retardation, which can be avoided by dietary restriction of phenylalanine beginning soon after birth.

**Polymorphism:** A single gene trait (e.g., red blood cell surface antigens) that exists in two or more alternative forms (such as types A, B, AB, and O blood). A genetic variant would be considered a polymorphism if its frequency exceeded 1 percent, but would be considered a rare mutation if found in less than 1 percent of the population.

**Predictive test:** A medical test generally applied to asymptomatic individuals to provide information regarding the future occurrence of disease. Compare *diagnostic test* and *screening test*.

**Predictive value:** The proportion of individuals with positive test results that have (or will have) the condition in question.

**Preexisting condition:** A condition existing before an insurance policy goes into effect and commonly defined as one which would cause an ordinarily prudent person to seek diagnosis, care, or treatment.

**Prevalence:** The number of existing cases of a specified disease or condition divided by the number of people in the total population at a point in time. Compare *incidence*.

**Radioimmunoprecipitation assay (RIPA):** An assay method based on antigen-antibody interactions, based on principles similar to enzyme immunoassays but using radioisotopes to measure the interactions. See also *enzyme immunoassay* and *indirect immunofluorescence assay*.

**Rated premium:** A premium with an added surcharge that is required by insurers to cover the additional risk associated with certain medical conditions. Rated premiums usually range from 25 to 100 percent of the standard premium.

**Recombinant DNA:** The hybrid DNA produced in the laboratory by joining pieces of DNA from different sources.

**Recombinant DNA technology:** The techniques for cutting apart and splicing together pieces of DNA from different sources.

**Reliability:** The consistency of measurement or degree of dependability of a measuring instrument.

**Restriction enzyme (or restriction endonuclease):** An enzyme that recognizes a specific base sequence (usually four to six base pairs in length) in a double-stranded DNA molecule and cuts both strands of the DNA molecule at every place where this sequence appears.

**Restriction enzyme recognition site:** The DNA site where a specific restriction enzyme cuts the DNA molecule.

**Restriction fragment length polymorphisms (RFLPs):** The presence of two or more variants in the size of DNA fragments from a specific region of DNA that has been exposed to a particular restriction enzyme. These fragments differ in length because of an inherited variation in a restriction enzyme recognition site. See also *polymorphism*.

**Retrovirus:** A virus that contains RNA, not DNA, and that produces a DNA analog of its RNA through the production of an enzyme known as "reverse transcriptase." The resulting DNA is incorporated in the genetic structure of the invaded cell in a form referred to as the "provirus."

**Reverse transcriptase:** An enzyme that produces a DNA analog of its RNA counterpart, reversing the usual process of gene expression during which the RNA analog of DNA is produced.

**Risk classification:** The evaluation of whether an insurance applicant will be covered on a standard or substandard basis, or not at all.

**Screening test:** Generally, a test used to sort out apparently well persons who probably have disease from those who probably do not. A screening test is not intended to be diagnostic. Compare *diagnostic test* and *predictive test*.

**Self-insurance:** Usually refers to the practice of employers, particularly large employers, of assuming the risks for the health care expenses of their employees instead of purchasing health insurance through insurance companies. Such employers often continue to contract with insurance companies or other organizations for claims processing and administrative services, as well as purchasing stop-loss insurance to limit the amount of their liability for medical claims. Similar arrangements exist in other lines of insurance; e.g., liability insurance.

**Self-pay:** See *individual health insurance*.

**Sensitivity:** One measure of the validity (or accuracy) of a diagnostic or screening test: the percentage of all those who actually have the condition being tested for who are correctly identified as positive by the test. Operationally, it is the number of true positive test results divided by the number of patients that actually have the disease (true positives divided by the sum of true positives plus false negatives). Compare *specificity*.

**Sickle-cell disease:** A potentially lethal recessive blood disorder caused by the mutation of a single nucleotide in the gene for beta-globulin, one of the protein chains that make up adult hemoglobin.

**Southern blotting:** A procedure for transferring DNA fragments from an agarose gel to a filter paper without changing their relative positions.

**Specificity:** One measure of the validity (or accuracy) of a diagnostic or screening test: the percentage of all specimens that do not have the condition being tested for that are correctly identified as negative by the test. Operationally, it is the number of negative test results divided by the number of specimens that actually do not have the condition (true negatives divided by the sum of true negatives plus false positives). Compare *sensitivity*.

**Standard risk:** A person who, according to an insurer's underwriting criteria, is entitled to purchase insurance coverage without extra premium or special restrictions.

**Substandard risk:** A person that does not meet the normal health requirements of a standard health insurance policy and whose coverage is provided with a higher premium and/or exclusion waiver.

**Tay-Sachs disease:** An autosomal recessive genetic disease resulting in developmental retardation, paralysis, dementia and blindness, usually fatal in early childhood. The defective gene codes for hexosaminidase A, an enzyme that is involved in certain chemical pathways in the brain.

**T4/T8 cell ratios:** The ratio of T4 cells (helper cells) to T8 cells (supressor cells). Individuals with AIDS have a deficiency of T4 cells and a reversal of the usual ratio of T4 and T8 cells.

**Thalassemias:** Recessively inherited blood disorders caused by various mutations which reduce the synthesis of one of the protein chains that make up hemoglobin. The victims of severe thalassemia require frequent blood transfusions and often die in their teens or early twenties.

**Third party administrators (TPAs):** A term originally used in the Taft-Hartley legislation of 1947 to designate an entity that is neither union nor management but administers joint labor-management welfare and pension funds. In self-insured health plans, TPAs typically provide administrative services such as medical claims processing, utilization and charges review, and data processing and reporting.

**Tumor marker assays:** Assays (e.g., immunoassays) that detect tumor-produced proteins.

**Underwriting:** The process by which an insurer determines whether or not and on what basis it will accept an application for insurance.

**Western Blot:** An assay designed to differentiate among several proteins present in the specimen, using electrophoresis and antigen-antibody interactions. Electrophoresis is used to separate proteins by their molecular weights, and each protein is subsequently identified through combining with their respective antibody or antigen. For example, in Western blot testing for HIV antibodies, the protein components of HIV are first separated electrophoretically, transferred to blots, then mixed with sera suspected of containing HIV antibodies. The presence of antibodies to specific proteins of HIV are revealed by the combination of antibodies with their specific protein components of HIV.

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## List of Related OTA Reports

- Staff Paper:

  —*AIDS and Health Insurance: An OTA Survey.* February 1988. GPO stock #052-003-01093-3; $2.75.

- Staff Paper:

  —*The Impact of AIDS on the Kaiser Permanente Medical Care Program (Northern California Region).* July 1988. GPO stock #052-003-01128-0; $2.25.

NOTE: Reports are available through the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402-9325, (202) 783-3238.

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## Chapter 1

# Summary and Conclusions

## INTRODUCTION

For the great majority of Americans, access to health care, and the health insurance that makes such access possible, is provided through the private sector. Medicare and Medicaid have played an indispensable role in making health care available to the indigent and near indigent, and to the elderly and some handicapped persons.[1] Yet there are approximately 31 million to 37 million people, or from 13.3 to 15.7 percent of the estimated 236 million persons living in the United States in 1986, who have no health insurance (table 1-1). An additional 8 to 26 percent of persons under age 65 have inadequate health insurance. (The estimates depend on the definition of "inadequate health insurance" that is used—see app. A.)

Persons who apply for health insurance on their own, instead of through group policies such as employment-based plans, usually have their health status evaluated by health insurers to determine whether or not they are in fact insurable. (This evaluation is commonly referred to as "underwriting.") For insurable applicants, some might be determined to be at such an added health risk to require higher than standard premium rates and/or insurance policies that exclude from coverage specified diseases or conditions that the applicant already has or is at significant risk of developing. Those with significant disease or risk of disease may be denied insurance altogether.

When underwriting individual applicants for health insurance, insurers rely at a minimum on a medical history questionnaire, and less frequently on such other sources of information as a statement from the applicant's attending physician or actual records from the physician, medical tests, and physical exams.

Advances in predictive and diagnostic medical testing are increasing our capability to identify individuals who are likely to develop serious diseases. The use of these tests by health insurers may (or may not) make private health insurance unavailable or too costly even to a number of presently insured persons and their dependents if analyses of their risks improve. Already, tests to detect the presence of antibodies to the AIDS virus (HIV, for "human immunodeficiency virus") have brought the issue of private health insurance availability to the forefront of public policy discussions on health insurance for persons infected with HIV.

**Table 1-1.—Percent Distribution and Number of Persons by Insurance Coverage Status, United States, 1986**

| Age | Coverage status | | |
|---|---|---|---|
| | All[a] | Covered[b] | Not covered[c] |
| | Percent distribution | | |
| All ages | 100.0 | 86.7 | 13.3 |
| Under 18 years | 100.0 | 85.4 | 14.6 |
| 18-24 years | 100.0 | 75.3 | 24.7 |
| 25-44 years | 100.0 | 85.2 | 14.8 |
| 45-64 years | 100.0 | 90.0 | 10.0 |
| 65 years and over | 100.0 | 99.3 | 0.7 |
| | Number in thousands | | |
| All ages | 236,348 | 201,830 | 31,010 |
| Under 18 years | 63,132 | 52,862 | 9,071 |
| 18-24 years | 26,721 | 19,751 | 6,466 |
| 25-44 years | 74,260 | 62,382 | 10,853 |
| 45-64 years | 44,698 | 39,708 | 4,418 |
| 65 years and over | 27,538 | 27,126 | 202 |

[a] Percent distribution excludes unknown coverage status; frequency includes unknown coverage status.

[b] Covered by private health insurance, Medicare, public assistance, or military-Veterans Administration health benefits.

[c] Not covered under any of the four health-care plans. Estimates range from 13.3 to 15.7 percent, or 31.0 to 37.2 million persons (see also app. A of the full report).

SOURCE: P. Ries, "Health Care Coverage by Age, Sex, Race, and Family Income: United States, 1986," *NCHS advancedata*, No. 139, Sept. 18, 1987.

People with individually obtained health insurance comprise only 10 to 15 percent of all persons with health insurance. Furthermore, group applicants for health insurance, who comprise 85 to 90 percent of all persons with health insurance and who obtain their health insurance predominantly through their workplace, seldom if ever are subjected to individual determinations of their health status. Premiums for group health insurance policies are usually "experience-rated," which is based principally on the actual health care costs most recently incurred by the group.

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[1] In addition, the medical care systems of the Department of Defense and the Veterans' Administration provide medical care to active and retired military persons, and to military veterans.

However, even persons presently insured through group health insurance are not exempt from the possibility of unavailable or unaffordable health insurance. Containment of ever-increasing health care costs is a high priority for employers, who also might be interested in using predictive medical tests to screen out prospective employees who might consume a disproportionate share of funds allocated to meet employee health care expenses. The increasing propensity of employers, especially large employers, to self-insure their employees' health care expenses is a reflection of the business community's concern over rising health care costs. Furthermore, although self-insured plans are subject to Internal Revenue Service and Department of Labor review and regulations, current law makes these self-insured health care plans free of State insurance department review and regulations, leading to fewer restraints on self-insured plans than on traditional health insurance plans for employers who might decide to use medical testing to decrease their employee health care expenses.

Such potential actions by the private sector have obvious consequences on public sector spending for health care. To what extent are such actions already occurring, what is the potential for their occurring, and what are the potential consequences if these actions are adopted on a wide scale by private insurers and the business community? Are the current availability of the AIDS antibody test, its ability to identify those infected with the AIDS virus, and the growing percent of infected persons who progress on to frank disease, forewarnings of these private-public sector issues? Will the way in which we address the financing of AIDS patients be a paradigm for how we should address the issues raised by the availability of other medical tests in the future, or does AIDS warrant a unique response?

*Current and future use of medical testing to determine health care insurability, and the impact that such use of medical tests by private health insurers could have on public financing of health care, prompted the request for this study* by the House Energy and Commerce Committee, its Subcommittee on Health and the Environment, and the Subcommittee on Intergovernmental Relations and Human Resources of the House Government Operations Committee. The request was supported by the Subcommittee on Health of the House Ways and Means Committee and by the Subcommittee on Natural Resources, Agriculture Research, and Environment of the House Committee on Science, Space, and Technology.[2]

The rest of this chapter summarizes OTA's findings and conclusions and provides options on major issues identified in this report.

Chapter 2 provides an overview of health insurance and the results of an OTA survey of the underwriting practices and AIDS claims experience of private insurers—commercial insurers, Blue Cross/Blue Shield (BC/BS) plans, and Health Maintenance Organizations (HMOs).

Chapter 3 describes the use of tests by employers to screen for medical and health-related conditions among prospective and current employees.

Chapter 4 describes current and future tests to diagnose or predict disease.

The Appendices include descriptions of the uninsured population and State developments in establishing high-risk insurance pools for persons unable to obtain health insurance. Two activities conducted as part of this assessment have been previously published.[3]

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[2] A letter of support for the study was also received from Senator Daniel K. Inouye (D.-Hawaii).

[3] *AIDS and Health Insurance: An OTA Survey* (February 1988) and *The Impact of AIDS on the Kaiser Permanente Medical Care Program (Northern California Region)* (July 1988).

## HEALTH INSURANCE UNDERWRITING

### Group v. Individual Insurance

The purpose of insurance is to minimize financial losses that may arise from unexpected events. Insurance operates by spreading risks over a number of people so that many individuals who could have a loss, but don't, help pay for the losses of the few that do sustain losses. Insurance works on the principle that there must be uncertainty that a loss will occur, and that the loss is beyond the control of the insured. The size of the potential loss is another factor and should ordinarily be of such magnitude that its occurrence has a significant financial impact on the insured. Private insurance operates on the principle that the cost of insurance generally should be proportional to the risk involved. Individuals whose potential losses are large are expected to pay more in premiums than those whose potential losses are likely to be less.

Although individual and group health insurance provide protection against similar types of medical expenses, they are, in a sense, fundamentally different types of insurance. An individual health insurance contract is one made by an insurer with an individual applicant and normally covers that individual, and, in some cases, his or her dependents. A group insurance contract is made with a sponsor, usually an employer, and the group sponsor, not the members of the group, is the insured party. Group insurance contracts are, as a rule, continuous in nature and ordinarily continue beyond the lifetime or membership in the group of any of its individual participants.

Group insurance is generally issued without medical information or other evidence of insurability of the individuals covered, and group underwriters are usually interested only in whether the group as a whole can be insured. Group underwriters will accept groups whose expected claims experience meets the standards established by an insurer for a plan of benefits and will set a rate to cover those expected costs. As noted earlier, larger groups are generally experience-rated, meaning that the premiums charged are based on the actual amount of claims payments made on behalf of the group in a prior period, usually the preceding year. In contrast, applicants for individual insurance are not part of a well-defined, homogeneous, and generally healthy group; and individuals are also free to apply for various types and amounts of coverage. The fundamental purpose of underwriting is to assure that insured persons within each risk class have the same probability of loss and probable amount of loss. Thus, "medical underwriting" is customarily used by most insurers to determine whether and under what terms individual insurance coverage will be approved.

## Adverse Selection

"Adverse selection" refers to the situation whereby, in the absence of any controls, persons who seek to obtain insurance will tend to be those who will use it the most; that is, those with a greater than average probability of loss. Applicants who are motivated to purchase coverage because they are aware of a medical problem that is not yet evident to the underwriter can select against the insurer. This is of concern in both group and individual insurance markets, but particularly in the latter. Group insurers try to protect themselves against adverse selection by using certain group underwriting techniques. For example, group insurers usually write coverage only for groups that exist for reasons other than for the purpose of obtaining insurance. There generally is a flow of members into and out of such groups so that the average age and therefore the average risks of these groups do not increase much over time. Employer-based groups are especially attractive to insurers, because employees whose health is good enough to meet employment standards are generally better-than-average risks for insurance purposes.

Adverse selection is a particular problem for the individual insurance market. Although most applicants are seeking coverage for the costs of unknown or unpredictable diseases, some applicants are especially motivated to obtain insurance, because they know they may have a higher than average probability or even a certainty that they will require medical treatment.

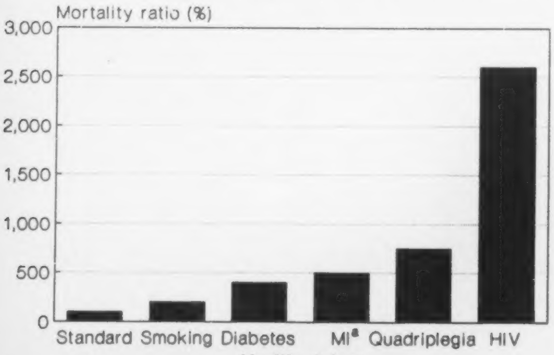
## Underwriting Factors

The goal of the underwriter is to determine whether and on what basis insurance can be issued at "standard" rates, offered at higher premium rates or with other limitations (such as excluding a specified medical condition from coverage), or whether insurance should be refused (declined) altogether. Each insurer prescribes its own range of acceptable risk selection factors.

For health insurance, age and current and future health status are the two most important risk factors. Claims costs for different benefits often vary by gender, so sex is also a factor. Most health insurers deny any applicant whose probability of disease exceeds three times the standard risk for his or her sex and age, and most life insurers will refuse an applicant whose risk of death exceeds five times the mortality risk of a person with no health impairment. HIV infection, for example, far exceeds the limit of insurability for both life and health insurance. Insurers estimate that the mortality risk of an HIV-infected person is 26 times that of a standard risk (figure 1-1), and that the mortality risk of an asymptomatic 35-year-old male infected with the AIDS virus is 44 times that expected for a healthy, non-HIV-infected 35-year-old male.

Two types of information are obtained from applicants for individual coverage. First, is the health history. A history of past illness or accident will be given weight depending on the severity of the original ailment, degree of permanent impairment (if any), possibilities of recurrence, complications that may develop, etc. Individuals with conditions that are chronic often have high costs and large claims and may be refused coverage. Certain family health information may be requested relating to the health of relatives that may have some bearing on the applicant's health (e.g., family history of diabetes). Second, the applicant's current physical condition is evaluated. Depending on this assessment, certain tests or studies may be requested (e.g., blood chemistry, urinalysis, electrocardiogram), depending on the age or kinds of coverage sought.

**Figure 1-1.—Comparison of Mortality Risks for HIV Infections and Other Selected Conditions**



[a] Myocardial infarction.

SOURCE: K. Clifford and R. Iuculano, "Acquired Immunodeficiency Syndrome (AIDS) and the Recommendations of the NAIC Advisory Committee on AIDS," statement to the Health Insurance (B) Committee of the National Association of Insurance Commissioners, Orlando, FL, Dec. 9, 1986.

## Regulation of Insurers

All of the States have established laws that require insurance companies to meet a variety of financial and other requirements in order to obtain a license to do business in each State. The general framework is similar, but the exact requirements vary widely from State to State. Certain amounts of financial resources needed to establish solvency as an insurer are ordinarily stipulated. Many States also require companies to maintain membership in a guarantee association, including financial participation in such an arrangement to cover the liabilities of impaired or insolvent companies.

While the substance of State regulation is similar to that of commercial insurers, hospital service (Blue Cross) and medical service (Blue Shield) plans are ordinarily exempted from State commercial insurance laws and are granted franchises to do business and are regulated under separate enabling legislation. In response to growing competitive pressures, an increasing number of BC/BS plans are seeking legislative approval to reorganize themselves as mutual insurance companies.

Group health insurance rates are based on past experience ("experience-rated"), and health insurance underwritten on a group basis has a history of being quite competitive. Regulation of individual health insurance contracts is somewhat more rigorous and also more standardized than for group contracts. This is due, in large part, to the view that the people who are individually insured lack expertise about many insurance matters and are not in a position to negotiate the terms of contracts with the companies that specialize in this field.

Some States require the advance approval of individual policies and related contractual materials (e.g., the application form). In many States, although information is provided to the insurance department, these materials will be deemed approved unless advised to the contrary within a specified period of time.

States frequently prohibit certain types of discriminatory practices in issuing, continuing, or canceling insurance policies, or prohibit charging higher premiums solely because of certain physical handicaps such as blindness, mental handicaps, etc., unless the discrimination can be justified by sound actuarial practice.

Many States have also adopted various mandated benefit laws. Alcoholism, drug addiction, and maternity coverage are frequently required. Some States require insurers to offer prospective buyers certain benefits, but the inclusion of those benefits in group contracts is often not mandatory.

Many States also have laws governing some aspects of group insurance contracts, such as who constitutes a group for group benefit purposes. Many States have also adopted laws requiring group contracts to contain certain types of mandatory conversion and/or continuation-of-coverage provisions, which permit members (and dependents) of a group to continue their insurance protection on an individual basis when their coverage under a group plan ceases. The continuation is an extension of the original group plan at the same premium, though the separated group member pays the full premium costs of coverage, including any employer contributions made on behalf of members still in the group. (The Federal Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Public Law 99-272) has a similar provision regarding continuation of coverage.)

States impose taxes on premiums received by insurance companies. These taxes vary from State to State, by the type of company involved, and whether the insurer is an out-of-State or domestic company. Most of the tax rates are in the 2 to 2.5 percent range. Most States do not impose premium taxes on BC/BS plans, though several States do impose some charges on them in lieu of premium taxes.

While the McCarran-Ferguson Act (Public Law 15, 79th Congress) provides that the States have the major regulatory responsibilities with regard to the business of insurance, several Federal laws affect health benefit plans, particularly group plans. Under the Federal tax code, employer contributions for health benefits are excluded from the taxable income of their employees. Legislation such as the Employee Retirement Income Security Act (ERISA), the Health Maintenance Organization (HMO) Act, and Medicare, each affect the design of many private health benefit programs. Congress has also enacted laws prohibiting certain discriminatory practices relating to age and sex in the provision of health benefits for employees and their dependents. And as mentioned above, the tax laws and ERISA were recently amended under COBRA to require that most group benefit plans continue coverage for workers and their dependents who would lose such protection due to job termination, death, divorce or legal separation, and for certain other qualifying events.

The most important competitive development in the group health benefits market during the last 15 years has been the movement toward self-insurance by large employers. Self-insured plans offer several key advantages to employers. Employers are able to use and retain earnings on amounts that would otherwise be paid to and held by insurers to create claims reserves. No premium taxes are applied to self-insured plans. Most importantly, self-insured plans can avoid the requirements of State insurance laws and regulations because of the Federal ERISA legislation. Thus, much of the group benefits marketplace is virtually unregulated by the States. Self-insured plans need not comply with any of the State laws that require health insurance contracts to include specific benefits or comply with anti-discrimination restrictions applied to insured plans, need not pay State insurance premium taxes, and need not participate in State insurance pools for high-risk individuals.[4]

## Results of the OTA Survey

Insurance testing for HIV infection has generated much controversy and disagreement among insurers, insurance regulators, insurance applicants, legislators, and other policymakers. Yet, there is little information on who insurers test and what tests they require. OTA therefore conducted a survey of commercial insurers, BC/BS plans, and HMOs in the summer and early fall of 1987. The OTA survey was an attempt to provide a view of HIV testing in the context of other routine tests required by health insurers and had a twofold purpose: 1) to collect basic information on underwriting practices and the use of medical screening by health insurers; and 2) to document how health underwriters are responding to the AIDS epidemic.

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[4] See Appendix B for description of State high-risk insurance pools.

Approximately 14.5 million individuals under age 65 (and their family members, when covered) have health insurance without the benefits of group membership. These are the individuals that must meet underwriting standards to obtain health coverage, and their insurers were the focus of the OTA survey. Commercial companies insure 9.3 million; BC/BS plans, 4.2 million; and HMOs, 1 million.

The survey was sent to 88 commercial insurers who comprise 70 percent of the commercial, individual health insurance market; to 15 of the 77 BC/BS plans; and to the 50 largest local and national HMOs in the United States. Seventy-three of the 88 commercial insurers responded, although only 62 met the survey requirements; approximately 57 percent of the commercial, individual health insurance market is represented in the survey findings. All 15 BC/BS plans completed the survey, and 39 of the 50 HMOs responded, but only 16 reported that they allow individually underwritten enrollment. Overall, 84 percent of the commercial carriers, BC/BS plans, and HMOs that were surveyed responded.

### Medical and Other Factors in Risk Classification

Approximately three-quarters of individual and small group applications for commercial health insurance were classified as "standard" by the responding insurers and obtained coverage without extra premiums or special limitations. Twenty percent of individuals and 15 percent of small group members were rated as "substandard" and issued policies that exclude preexisting medical conditions, had a higher than standard premium, or both. The exclusion may be for a specific condition, such as gallstones, or for an entire organ system, such as reproductive disorders. Finally, 8 percent of individual and 10 percent of small group applications were judged uninsurable and denied coverage. Most serious diseases were uninsurable, including severe obesity, diabetes mellitus, emphysema, alcoholism, coronary artery disease, cancer, schizophrenia, and AIDS.

Risk classification by the responding BC/BS plans was similar to the commercial approach except for four "open enrollment" plans that accepted all applicants regardless of health status. The respondents accepted 83 percent of individual applicants as standard, 9 percent with substandard policies, and denied coverage altogether to 8 percent. Sixty to 100 percent of small group applicants were also accepted as standard by half the plans, and up to 25 percent were denied.

HMO risk classification differed from the others. Federally qualified plans are restricted to either accepting applicants at a community rate or denying membership altogether. As a result, exclusion waivers and substandard premiums are not common. The responding HMOs, however, were no more willing to underwrite high-risk applicants than the commercial insurers or BC/BS plans. They accepted 73 percent on a standard basis and denied membership to 24 percent of individual applicants.

Other factors besides ill health can seriously hamper access to commercial health coverage by individual applicants and their family members. Dangerous health habits (e.g., drug abuse), suspected criminal association or unethical behavior, age, occupation, and financial status were most commonly cited by commercial insurers as critical to determining insurability. Healthy habits, such as nonsmoking, were also rated as important, an indication of the increasingly common use of premium credits for nonsmokers. Place of residence was an important factor to a significant minority of commercial insurers, mostly due to concerns about insurance fraud known to occur in certain localities and because of regional variations in health care costs. Contrary to guidelines proposed by the National Association of Insurance Commissioners (NAIC), 18 companies used sexual orientation in underwriting, and 5 of these companies considered it important or very important. (These 18 companies held approximately 10 percent of the individual, commercial health insurance market. Five were among the 25 largest in the country.) Three companies requested an attending physician statement (APS), and two ordered a physical exam based on sexual orientation. It is unclear how insurers ascertained an applicant's sexual preference. Most of the respondents (48 of 61) provided samples of their health insurance applications, none of which included any questions concerning sexual orientation or lifestyle.

In contrast, BC/BS insurability was almost purely a question of medical condition. All the responding BC/BS plans, except the four that hold open enrollment, rejected some applicants in poor health. Nearly half of the plans denied nongroup applications because of alcohol or drug abuse. No BC/BS plan reported using sexual orientation in underwriting.

Access to HMO membership was fundamentally a matter of health status as well. However, age, type of occupation, health enhancing behavior (e.g., nonsmoking), and sexual orientation were also considered key to insurability by 19 percent or more of the responding plans. As in the case of the commercial carriers, it is not clear how sexual orientation was identified by the four HMOs that considered it a key underwriting factor.

Health insurance applicants were rarely subjected to physical examinations and medical tests. Only 4 percent of individual and 2 percent of small group applicants to the responding commercial insurers were required to have a physical exam or some type of blood and/or urine test. Just two of the BC/BS plans required physical exams; one also required medical tests for some of its individual and small group applicants. Only three of the HMOs sometimes required physical exams or medical tests.

Beyond the health information provided directly in insurance applications, information provided by the applicant's physician (the "attending physician's statement," or APS) was the most common supplemental source of information. The commercial carriers required an APS for 20 percent of individual and 18 percent of small group applicants. Late applicants to large groups were also often required to furnish an APS. Almost three-quarters of BC/BS plans ordered a physician statement for at least 30 percent of their individual applicants, and more than half required an APS for up to 40 percent of small group applicants. Half or more of the responding HMOs requested an APS for 10 to 85 percent of their nongroup applicants and 10 to 20 percent of small group applicants. In fact for most applicants, in lieu of ordering a laboratory test for medical reasons, traditional insurers and HMOs alike usually relied on the test results reported by the applicant's physician. HIV testing was an exception in a few cases: three responding commercial carriers required an HIV test on every applicant in areas of high prevalence, such as New York and California.

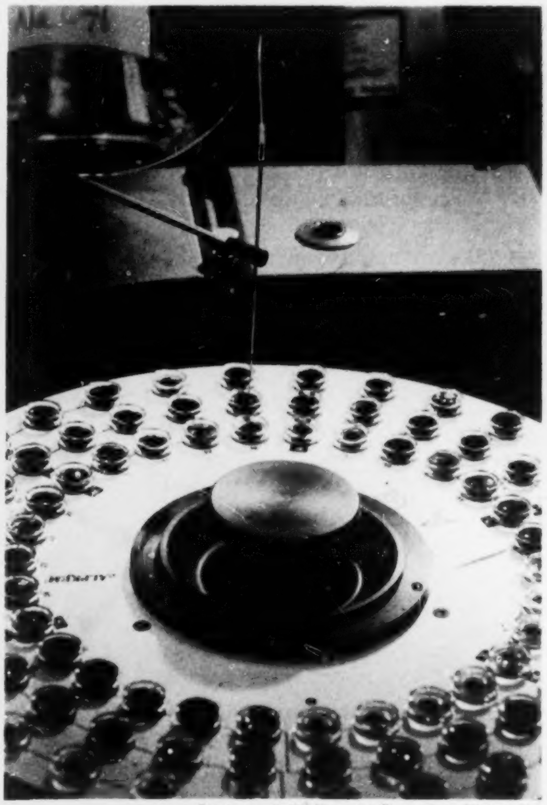

*Photo credit: Hoffman-La Roche Inc., Nutley, NJ.*

Automated testing procedures include a volume fill check, one of several quality control measures to ensure exactly the right amount of reagent in each bottle.

### AIDS Policies

Fifty-one (86 percent) of responding commercial insurers either screened or planned to screen individual applicants for HIV infection; 41 already did it and 10 planned to. Efforts to identify high-risk group applicants were also common. Twenty-seven small group (77 percent) and 11 large group insurers (58 percent) either screened or planned to screen through some method. The most common approach was by incorporating questions in the health history portion of the application. Asking AIDS-related questions is necessary to screen out preexisting conditions. If an applicant knowingly misrepresented his or her health condition (e.g., recognized symptoms of AIDS or fully diagnosed AIDS or AIDS-Related Complex (ARC)), the insurer may have grounds for denying reimbursement for the condition or rescinding coverage altogether. An admission of AIDS, ARC, or HIV seropositivity results in immediate denial of the application. Forty-two companies (82 percent) request a physician statement for selected, individual applicants in order to determine the presence of AIDS symptoms or other risk factors. (The APS may contain the applicant's HIV status as well.) Eighty-one percent of small group (22 of 27) and 64 percent (7 of 11) of large group insurers also screen this way. HIV testing was also quite common. Thirty-one companies routinely tested individual health insurance applicants for HIV antibodies: of these, 7 tested all applicants, 14 tested only those considered to be "high-risk," and 10 tested according to various criteria (e.g., State of residence, medical history, policy amount, etc.). All those who tested use the ELISA-ELISA-Western blot series. In States and localities where HIV testing is prohibited, 17 insurers required T-cell subset studies as a substitute. HIV testing is less common among the responding group insurers; only 9 of the small group (33 percent) and 3 of the large group insurers (27 percent) require an ELISA and Western blot for some applicants. T-cell subset studies are also used by 6 small group (22 percent) and 3 large group insurers (27 percent).

Eleven of the responding BC/BS plans either screened or planned to screen individual applicants for AIDS or ARC-related diagnoses; of these, eight already did, and three planned to. BC/BS efforts to identify high-risk group applicants are also common. Ten small group (77 percent) and seven large group plans (54 percent) either screened or planned to screen through some method. Eleven plans ask an AIDS-related question in their nongroup applications. If applicants answer that they have had or have been treated by a physician for AIDS or ARC, coverage is denied. As in the case of the commercial insurers, BC/BS plans ask about AIDS to screen out preexisting conditions. In addition, nine plans (82 percent) may ask for an APS to help evaluate a nongroup applicant's risk for AIDS. Seventy percent of small group (7 of 10) and 57 percent of large group plans (4 of 7) also order an APS for this reason. Only one BC/BS plan intended to test high-risk applicants for HIV infection.

Half or more of the responding HMOs screened or planned to screen individual (8 of 15) and small group applicants (4 of 8) for infections with the AIDS virus by one method or another. Three of the plans that do not are prohibited from doing any medical screening by State law. All the plans that screen ask an AIDS-directed question in the health history portion of their enrollment form. As in the case of the commercial insurers and BC/BS, an admission of AIDS, ARC, or HIV seropositivity results in denial of the application, and the AIDS-related questions on the application are used to screen out preexisting conditions (where allowed). Six plans request an APS to help determine an individual applicant's risk for AIDS; two plans similarly screen small group applicants. HIV testing of high-risk, individual applicants is done by only two plans and was under consideration by a third. No plan reported testing group applicants or using the T-cell subset test.

### AIDS Claims Experience and Cost Projections

Forty-five commercial insurers had reimbursed at least one individual policyholder for AIDS-related care. More than half of the respondents reported 10 AIDS cases or less, while 4 had reimbursed more than 50 individuals. On average, each insurer covered the care of 22 AIDS-related cases. (Of the remaining responding insurers, 6 reported no AIDS-related cases, 10 were unable to report their experience, and 1 had recently withdrawn from the individual market.)

Of the 20 insurers providing AIDS case data for their small group policies, 6 reported no AIDS-related cases and 14 had from 1 to 50, totaling 146. Twenty-two large group insurers reported 613 AIDS-related cases; 3 had no cases, 12 had less than 10, 6 had 11 to 60, and 1 company alone had 350.

Twenty-one individual insurers provided projections of AIDS-related claims costs for 1987, forecasting total claims of $11.04 million for individual health insurance, an average of $0.53 million per insurer. Two companies did not expect any AIDS cases in 1987—both specialize in insurance for seniors—while four projected costs of $1.3 to $2.3 million for individual health policies. (Cost projections were not furnished by 40 companies.) Twenty-two insurers who had received at least 1 AIDS-related claim reported linking no one with a preexisting condition for AIDS; 11 found 1 to 9 percent of cases to be preexisting; 10 companies, 10 to 50 percent; and 2 companies, more than 60 percent.

Seven small group insurers forecast a total of $1.5 million AIDS-related costs for 1987, ranging from none at one firm up to $618,000 at another. Seven large group insurers projected a total of $489,000 and an additional company reported that it expected 1987 AIDS-related group claims to total $5 million to $10 million.

Ten BC/BS plans reported reimbursing 3,933 subscribers for AIDS-related care, an average of 393 subscribers per plan (although one plan alone accounted for 3,000 cases). (The BC/BS plans' AIDS case and cost data reflected both individual and group policy experience.) The 7 plans that never hold open enrollment reported a total of 453 AIDS-related cases, an average of 65 subscribers per plan. Three of these plans are located in areas of high AIDS prevalence. In contrast, the 3 plans that are continuously open (and thus never screen) reported reimbursing 3,480 subscribers for AIDS-related care, an average of 1,160 cases per plan. Two of these plans are in areas of high AIDS prevalence, and all three have held large market shares. Only five plans provided 1987 projections of AIDS-related costs. Three nonopen enrollment plans (two are located in high prevalence areas) forecast a total of $29.6 million in AIDS-related claims for 1987. Claims totaling $27 million were projected by two open enrollment plans; $20 million at one plan alone. Eight of the 10 plans that have identified at least 1 subscriber with AIDS reported finding that 1 to more than 50 percent of these subscribers had a preexisting condition for AIDS. Two of these plans, both in areas of high AIDS prevalence, connected more than half of their AIDS cases with a preexisting condition.

Twelve HMOs reported 1,468 members with AIDS or ARC, an average of 122 members per HMO. The range varied from none at 2 HMOs to 940 patients at 1 HMO. (The HMOs' AIDS case and cost data reflect their individual and group membership experience.) Only two HMOs provided projections of AIDS-related costs for 1987. One plan that had identified 10 cases during the first 10 months of 1987 forecast total costs of $750,000 for the year; the other had 11 cases in the year preceding September 1987 and forecast total costs of $700,000 for 1987. (An additional HMO did not project 1987 costs but estimated that its diagnosed members had average lifetime costs of approximately $35,000.) One HMO, located in a high prevalence area, reported that more than half of its individual members with AIDS or ARC were found to have a preexisting condition. According to State law and in contrast to the other insurers, this plan was obligated to provide services for preexisting conditions (without a waiting period) unless the applicant had deliberately misrepresented his or her health status before joining the HMO.

The commercials, BC/BS plans, and HMOs reported similar methods to reduce their exposure to the financial impact of AIDS. These activities included reducing exposure to individual and small group markets by tighter underwriting guidelines, expanding the use of HIV and other testing, adding AIDS questions to the enrollment applications, and denying applicants with a history of sexually transmitted diseases. Two commercial insurers intended to place dollar limits on AIDS coverage in new policies, and one was introducing a waiting period for AIDS benefits. One HMO intended to withdraw from the individual health insurance market altogether, and a commercial carrier reported withdrawing from the District of Columbia. A BC/BS plan intended to lengthen the waiting period for new subscribers with a history of hepatitis, lymph disease, and mononucleosis, and two others were expanding their AIDS education efforts.

## TESTING BY EMPLOYERS

There are reasons other than concern over health care costs for which employers might want to screen their prospective as well as current employees. First, screening may be used as part of a preemployment evaluation to disqualify applicants (e.g., testing for illegal drug use) or to determine if the applicant can physically perform the intended work (e.g., examinations for firefighters and police). Second, after a person is hired, screening may be used to determine whether there is any health condition that may require special precautionary care because of workplace exposures. Third, screening may be used to monitor workers exposed to known or suspected environmental hazards, including preplacement testing to establish a baseline that can be used for comparison with future worksite monitoring results. Finally, screening may be incorporated into workplace wellness programs to identify risk factors associated with certain diseases so that these factors can be reduced through health education.

Incentives to screen prospective employees may be much more significant for some employers than for others. Employers with low turnover and high training costs may be especially interested in preemployment screening. Similarly, employers with generous health care and disability benefits may be more inclined to screen than employers with limited benefits. On the other hand, employers with high employee turnover may not have incentives to test for disease susceptibilities if new employees are young and likely to be employed elsewhere when these diseases become manifest. However, these same employers might have greater incentives to test for illegal drug use because of greater use among younger workers.

A wide variety of legal restraints is potentially applicable to employment-based screening, although much remains unsettled in this area. Distinctions must also be made as to whether the employer is in the public or private sector (i.e., whether governmental action is involved); whether a cause of action by a prospective employee who objects to testing is grounded in an existing statute or in case law as developed over the years by the courts; and for employees, whether or not they are represented by unions and have the additional protection of collective bargaining agreements. Additionally, States differ in their approaches and available legal remedies, so the State in which a cause of action is brought may also have a substantial bearing on the success or failure of challenges to testing.

The principal statutory remedy available to persons objecting to employment-based testing is the Vocational Rehabilitation Act of 1973 (29 U.S.C. sections 701-796), which applies to Federal employment and to employers who receive Federal funds. In addition, over 40 States and the District of Columbia have legislation prohibiting handicap discrimination in private sector employment, and while the definitions and judicial interpretations of what constitutes a handicap vary by State, about one-third follow the Federal law.

Handicapped persons must be hired or continue to be employed if they can be reasonably accommodated and can perform their work without endangering the health and safety of other workers. In March 1987, in the case of *School Board of Nassau County, Florida* v. *Arline*,[5] the United States Supreme Court ruled that a person with tuberculosis was a handicapped person within the meaning of the law and that contagiousness did not automatically remove the person from the Act's protection. The Court, however, expressly stated that it was not ruling on whether a person infected with the AIDS virus but without disease would come under the Act's protection.

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[5] 107 S.Ct. 1123, *reh. denied*, 107 S.Ct. 1913 (1987).

## The Extent of Employment-Based Medical Testing

### Physical Examinations

Perhaps the most prevalent type of medical screening used by employers is the general physical examination, including the use of blood chemistry profiles and urinalyses of the same types used by the insurance industry. For example, according to surveys by the National Institute for Occupational Safety and Health (NIOSH), the percent of employers who require job applicants to pass medical screening exams increased from 38.5 percent in the early 1970s to 49 percent in the early 1980s. These exams seem oriented toward improving or maintaining the employee's health, because companies with industrial hygiene and safety programs, and/or unionized companies, are more likely to provide medical screening than other companies.

The use of physical exams and medical testing is associated with company size and type of business. The larger the company, the more likely that physical exams and screening tests will be conducted. Employees in transportation and public utility industries are most likely to have preemployment examinations; in 1981-83, an estimated 73 percent of employees in these industries were screened, followed by 69 percent in the services industry, and 62 percent in the manufacturing industry. In 1981-83, an estimated 36 percent of employees had blood tests, and 35 percent had urine tests. In plants employing more than 500 workers, periodic medical screening included blood and urine testing for 69 and 66 percent of all workers, respectively. Blood testing was most prevalent in the service industries, where an estimated 60 percent of workers were screened.

### Genetic Testing

Genetic testing to screen individuals for hypersusceptibility to hazardous materials has been controversial, because genetic traits frequently are associated with particular racial or ethnic backgrounds.

In a 1982 OTA survey of the 500 largest U.S. industrial companies, 50 of the largest private utilities, and 11 large labor unions, only 6 of the 366 organizations who responded to the survey were then conducting genetic testing, 17 had used some of the tests in the past 12 years, 4 anticipated using the test in the next 5 years, and 55 thought it possible that they would use the tests in the next 5 years.

In a 1986 OTA survey of 120 biotechnology companies that were developing or likely to develop genetic tests for commercial use, of 85 respondents, 12 were developing or planned to develop tests for human genetic conditions. Of these 12 companies, employment-based testing and insurance testing were far down the list of possible uses. In descending order of importance, these companies rated likely sites of use as: genetic clinics; health department clinics; health department screening programs; prepaid health groups; private primary care practices; and sites such as reference and DNA labs, insurance companies, the military, places of employment, private nongenetic specialty practices, correctional institutions, public schools, and homes.

### Drug Use Testing

Various surveys have documented the increasing tendency of both private and public sector employers to screen applicants and to test employees for use of illegal drugs. Based on these surveys, perhaps half or more of employers, especially large employers, now test or plan to test for drug use. For example, of the Fortune 500 companies, urine drug testing for job applicants and/or current employees increased from 10 percent in 1982, to approximately 25 percent in 1985, to an expected 50 percent in 1987.

In a 1986 survey by the College Placement Council, whose members recruit on college campuses, the most common reasons given for drug testing were concerns over workplace safety (by far the most important reason); security; quality/reliability of products; quality of service; increased productivity; control of medical costs; and law, government, or noncompany regulations. The types of employers most likely to test job applicants were utilities (37.1 percent); chemicals, drugs, and allied products (9.3 percent); aerospace (8.6 percent); and petroleum and allied products (7.9 percent). Nearly all screened all applicants,

Photo credit: Home Office Reference Laboratory, Shawnee Mission, KS

A rapid flow analyzer used for the quantitative determination of glucose in human plasma.

whether for management, clerical, or technical positions, and most screened applicants whether they were seeking full-time, part-time, or temporary positions.

These trends are found among both private and public sector employers, including the Federal government.

### AIDS Antibody Testing

According to the Centers for Disease Control (CDC), there is no justification for excluding AIDS or antibody-positive individuals from the workplace on the grounds of risks to coworkers, and CDC also recommends against routine testing in the workplace.

Except for a few employers who have tested job applicants and/or employees for infections with the AIDS virus, employers have generally rejected AIDS antibody testing and support education as the best way to deal with AIDS among their employees. There appears to be a relationship between support of testing and knowledge of the ways that AIDS can be spread. There is also a substantial gap between what employers say should be done versus actually developing educational strategies and programs for their employees. For example, in one survey (by the magazine, *Business Week*) in early 1987, employers were asked what they would do if a coworker objected to working with an employee with AIDS. Eight percent of respondents said they would move the employee with AIDS; 14 percent would move the coworker; 29 percent would insist that the situation continue unchanged; 3 percent would take none of these actions; and 46 percent were not sure what they would do.

Employers who have had to face AIDS among their employees have generally treated AIDS as they have treated other illnesses. Many employers who find they have employees with AIDS try to accommodate those individuals so that they can continue to work as long as possible and keep their health benefits coverage through the company's health plan.

Most businesses have not yet taken action to monitor employees with AIDS because most have not had experience with such employees. However, there are indications that AIDS-related health care costs (and disability and life insurance costs) may be increasing for some employers to the point that employer attitudes may change. The costs of treating AIDS was not a major issue for employers in 1985. By the next year, 1986, among 1,500 surveyed businesses in 36 States representing 4.4 million employees, 3 percent of responding employers were measuring the cost impact of AIDS, and 2 percent indicated they were modifying the design of their health plans. By late 1987, surveyed companies with AIDS among their employees reported an increase of 4.5 percent from AIDS in their expenditures for health care, and expected AIDS-related care to increase their health care expenditures an additional 16 percent by 1990. (The highest percentage increases among these companies were for life insurance costs, up nearly 28 percent from AIDS, but employers expected to gain more control over these costs so that increases in life insurance costs would be limited to 7 percent by 1990.)

Additional pressure on employers' health care costs from AIDS among their employees comes at a time of extreme health care cost-consciousness on the part of businesses. With the high rates of health care cost inflation since the mid-1970s and the increased health insurance premiums that have accompanied these rates, employers have sought ways to shift more of the costs to their employees. Surveys have shown that many employers have increased their employees' share of health care costs and modified health plans to encourage use of less costly services, and more large employers are turning to self-insurance instead of purchasing health insurance through insurers.

The rapid growth of self-insurance does raise special concerns related to medical testing in the workplace. Because there is little regulation of self-insured health plans, medical conditions such as AIDS could affect employees of self-insured employers differently than employees of employers with conventional insurance, because self-insured employers have different means of responding to the problems of high-cost employee health benefit claims.

# DIAGNOSTIC AND PREDICTIVE MEDICAL TESTING

## Tests Currently Used by Insurers

Information on the types of medical screening tests used by insurers is based on testing of both life and health insurance applicants. The great majority of testing is in the life, not health, area, because individual life insurance applicants greatly outnumber individual health insurance applicants.

Most of the tests used by insurers are commonly used by clinicians and include blood biochemical profiles and routine urinalyses. Both blood biochemical profiles and urinalyses are mainly directed at uncovering evidence of underlying kidney, liver, and cardiovascular diseases, and diabetes. However, when applied to asymptomatic populations, these tests are not very predictive of disease. For example, in the case of serum glucose, although approximately 2 percent of asymptomatic adults have repeatedly elevated values, less than 17 percent are found to be diabetic. Because of their poor predictive value, professional guidelines recommend that they be administered on the basis of clinical findings. There is evidence that commercial insurers are limiting the use of biochemical profiles and urinalyses to selected high-risk applicants.

Insurers may also screen for evidence of use of specific prescription drugs, for drugs of abuse, and more recently, for evidence of infection with the AIDS virus.

There are two reasons to screen for prescription drug use: 1) to indicate the level of patient compliance with medically prescribed treatment—i.e., whether the applicant is in fact using the medications his or her physician has prescribed; or 2) as evidence that an applicant is undergoing treatment for a medical condition he or she has not divulged on the medical questionnaire. The most common medications tested for are drugs to treat cardiovascular diseases such as hypertension and heart disease (e.g., diuretics and beta-blocker drugs) and diabetes (e.g., hypoglycemic or blood-sugar-lowering drugs).

The most frequently tested drugs of abuse are nicotine and cocaine, with the nicotine test used to confirm that applicants are nonsmokers because of the increasing use of nonsmoker discounts (for life insurance applicants) by insurers. Abusers of illegal drugs are considered uninsurable by many companies.

Tests to detect evidence of infection with the AIDS virus are also being used. In 1986 the Home Office Reference Laboratory, Inc. (HORL), the principal lab used by life and health insurers, performed more than 128,000 tests for antibodies to the AIDS virus, using the ELISA screening test

Photo credit: Abbott Laboratories, North Chicago, IL

Preparation of samples for abused drug testing.

and the Western blot confirmatory test for ELISA-positive blood specimens. HORL also performed more than 25,000 T-cell tests, one of the tests that is used to indicate immune function status and used by insurers where use of AIDS antibody testing is prohibited (principally California). During this same period, HORL performed 213,000 routine blood tests. Thus, if we assume that persons who had HIV antibody or T-cell testing also had routine blood testing performed, approximately 70 percent of persons undergoing blood testing by the insurer clients of HORL were also tested for signs of infection with the AIDS virus.

The types of blood and urine tests conducted by HORL for insurers in 1986 are summarized in table 1-2.

## Tests of Interest Because of High Prevalence and Physician Screening Practices

Tests to predict cancers and heart disease or to uncover these diseases in their latent stages may be of interest to insurers.

Screening tests for latent disease are available for several of the most common cancers; such as, colon, breast, and uterine/cervical cancers. However, although effective in reducing mortality when applied to age-appropriate populations, most available screening tests will miss a significant percentage of individuals who should test positive (referred to as a test's "sensitivity"), and conversely, will be positive in many individuals who do not have the indicated disease (a test's "specificity"). Furthermore, the follow-up tests required to correctly identify those with cancer are expensive and invasive.

For example, tests to detect occult blood in the feces are estimated to detect only 25 to 35 percent of colon polyps and only 70 to 90 percent of colon cancers. Furthermore, of the positive tests, only 52 percent would represent true cases of either polyps (40 percent) or cancer (12 percent). Although the test is inexpensive to administer and interpret, a positive result would need to be further evaluated by direct and/or indirect visualization of the colon through sigmoidoscopy/colonoscopy and/or air-contrast barium enema x-ray studies. The costs of evaluating a positive result can therefore be as high as $1,000. Because of the relatively low accuracy of the fecal occult blood test, the American Cancer Society recommends that, in addition to occult blood testing, persons over 50 years of age have yearly sigmoidoscopies for 2 years, followed by similar exams every 3 years.

Available tumor marker assays could be used to identify applicants with cancer. For example the carcinoembryonic antigen (CEA) test is positive in more than 80 percent of advanced-stage colon cancer and 40 percent of early-stage cancers. However, the test is not very predictive of disease. When applied to asymptomatic populations, only 12 percent of positive tests represent CEA-associated cancers. However, sources of false posi-

**Table 1-2.—Blood and Urine Tests Used by Commercial Insurers (as reported by Home Office Reference Laboratory)**

| Blood tests | Associated conditions |
|---|---|
| Glucose | Increased glucose associated with diabetes mellitus, glucagonoma, mineralocorticoid excess (many causes), and hyperthyroidism. |
| Blood urea nitrogen (BUN) | Increased BUN associated with primary renal disease (e.g., medullary cystic kidney, hereditary nephritis), secondary renal disease (e.g., infectious, immunologic, vascular, metabolic, obstructive), and prerenalazotemia. |
| Creatinine | Increased creatinine associated with abnormal kidney function (see BUN). |
| Uric acid | Increased uric acid is associated with gout, renal failure, myeloproliferative disorders, and leukemia. |
| Total protein | Increased total protein is associated with systemic infection (e.g., tuberculosis), systemic inflammation (e.g., collagen vascular disease), malignancy (e.g., lymphoma, myeloma), and liver disease (many causes). |
| Albumin/Globulin | Decreased albumin is associated with malnutrition, nephrotic syndrome (many causes), protein-losing enteropathies (many causes), severe liver disease (many causes). |
| Aspartate aminotransferase (AST, formerly serum glutamic-oxaloacetic transaminase or SGOT) | Increased AST is associated with hepatocellular inflammation (many causes), cardiac inflammation (e.g., infarction, myocarditis, pericarditis), skeletal muscle inflammation (e.g., viral infection, polymyositis). |
| Alkaline phosphatase | Increased alkaline phosphatase is associated with liver disease (many causes), bone disease (many causes). |
| Glycohemoglobin (HBA1c) | Glycohemoglobin test measures the percentage of hemoglobin molecules that have glucose attached to them. Glycohemoglobin measurements indicate blood sugar activity during the six to eight weeks prior to the test and are therefore a measure of the success or failure of diabetic management. Test may be used as a diabetes screening test among asymptomatic individuals. |
| Bilirubin | Elevations associated with liver disease (e.g., cirrhosis), gall stones, pancreatic cancer, and some anemias. |
| Alanine amino transferase (ALT, formerly called SGPT or serum glutamic pyruvic transaminase) | Elevations associated with heart muscle damage, liver cell destruction, pancreatitis, infectious mononucleosis, some muscle diseases, and rickettsial infections. |
| Gamma-glutamyl transpeptidase (GGT) | A sensitive (but non-specific) indication of liver function. Elevations associated with alcoholism, recent myocardial infarction (within one month), cholestasis, nonalcoholic liver disease, and porphyria cutanea tarda. |
| Cholesterol | Increased cholesterol is associated with primary (e.g., familial) and secondary (e.g., hypothyroidism, nephrotic syndrome, hepatitis) hypercholesterolemia. Decreased cholesterol is associated with hyperthyroidism, malabsorption, liver disease (many causes), and abetalipoproteinemia. |
| Triglycerides | Elevations associated with hyperlipidemia (Type I). |
| High-density lipoprotein (HDL) | Elevation of HDL is associated with a decreased risk of heart disease. |
| Apolipoprotein A1 (Apo A1)-protein is associated with HDL | Elevation of Apo A1 is associated with a decreased risk of heart disease. |
| Apolipoprotein B (Apo B)-protein is associated with LDL | Elevation of Apo B is associated with increased risk of heart disease. |
| Antibodies to Human Immunodeficiency Virus (HIV) | Presence of HIV antibodies presumes infection with HIV and risk of developing acquired immunodeficiency syndrome (AIDS). |
| T-cell-lymphocyte typing | Suppression of T cells, a sign of immunodeficiency, is associated with several conditions: e.g., AIDS, CMV, mononucleosis, and autoimmune disorders such as systemic lupus erythematosus. |
| *Urine tests* | |
| Protein | Protein in urine is associated with kidney disease. |
| Glucose | Diabetes Mellitus. |
| RBCs | Kidney disease, bladder injury. |
| Casts | Kidney disease. |
| WBCs | Kidney disease, infection of urinary tract, bladder, kidney. |
| Tests for prescription medications (e.g., diuretics, beta-blockers, hypoglycemic agents) | Presence of prescription medication in urine is evidence that the patient is being treated for related conditions—e.g., hypertension, heart disease, hypoglycemia—and may indicate level of patient compliance with treatment. |
| Tests for drugs of abuse (i.e., nicotine, cocaine, other drugs of abuse) | Presence of drug in urine is evidence of drug use (but not impairment). |

SOURCES: H.C. Sox, Jr. (ed.), *Common Diagnostic Tests: Use and Interpretation*, (Philadelphia, PA: American College of Physicians, 1987); and C. Pinckney, and E.R. Pinckney, *The Encyclopedia of Medical Tests* (New York, NY: Facts on File, Inc., 1982).

tive results include hepatitis, ulcerative colitis, gastric ulcer, and renal disease, all of which would likely lead to exclusion or coverage on a nonstandard basis. Although these markers have been available for many years, they have not been adopted by insurers, because they are not accepted as screening tests by the medical profession.

A new test is being investigated that may be applied as a universal screening tool for cancer. The test is based on differences found between the lipid parts of lipoprotein particles (called "oncolipids") found in the plasma of patients with cancer as compared to those without cancer. The differences can be detected using magnetic resonance imaging (MRI). While the test has been shown to successfully distinguish those with some types of cancer from healthy individuals and from those with illnesses other than cancer, there are two significant sources of false positive results—pregnant women and men with noncancerous prostatic hyperplasia. In addition, individuals who have been succesfully treated for cancer continue to test positive. Although currently expensive to administer, the test could be automated and used for screening in the future.

Current methods to identify those susceptible to heart disease rely on tests for symptoms of disease, such as the EKG, or on an analysis of known heart disease risk factors. The three principal predictors of coronary heart disease (CHD), other than age and sex, are hypertension, elevated levels of cholesterol, and cigarette smoking. The risk of developing CHD can be determined by evaluating these factors (and other risk factors, such as diabetes) singly or in combination. For example, the relative risk of developing CHD within 18 years for a 35-year-old male with only high cholesterol, compared to a similar male with normal cholesterol, is 3.9. The relative risk increases to 23.2 when both cholesterol and blood pressure are elevated. Generally, smokers have more than twice the risk for a heart attack than nonsmokers.

Cholesterol screening is being actively promoted by heart disease experts. These efforts have been somewhat hampered by a lack of uniform laboratory quality in the conduct of-cholesterol measurement. Measurements of cholesterol, lipoproteins (e.g., high density lipoprotein or HDL, and low density lipoprotein or LDL), and the protein components of lipoproteins (apolipoproteins) are used in the evaluation of CHD risk. Levels of specific apolipoproteins are the most useful in distinguishing healthy individuals from those with CHD. Apolipoprotein tests can be conducted using automated instrumentation and are currently performed by commercial insurers.

As in the case of predictors for cancer, with available testing methods there will be many who will develop heart disease among those predicted to be at low risk, and many at high risk will remain disease-free. Therefore, although the presence of known risk factors raises the relative risk, the absolute risk remains low.

The prevalence of alcohol abuse or dependence is estimated to be between 8 and 10 percent among men and between 1 and 2 percent among women. The health consequences of alcohol abuse are considerable, and the biochemical profiles currently used by commercial insurers are used to detect the effects of alcohol abuse (e.g., liver disease). Structured questionnaires and laboratory indicators are available to help identify individuals with drinking problems. Evaluations of these screening methods have shown that structured questionnaires are more effective than most laboratory tests. Preliminary research on a biologic marker for alcoholism shows promise (i.e., inhibition of the enzyme, monoamine oxidase, by ethanol and stimulation of the platelet enzyme, adenyulate cyclase). In one study, this marker was used to correctly categorize 75 percent of alcoholics and 73 percent of nonalcoholics. Abnormalities were detected in alcoholics who had abstained from alcohol consumption, suggesting that the test may be a measure of the underlying basis of alcoholism. Further research will be necessary to clarify the utility of this marker.

## Methods of Interest for Future Testing

Advances in molecular genetics have led to the development of a number of new diagnostic and predictive tests. While several recombinant DNA-based diagnostic tests are now being marketed in the infectious disease area, a larger market may be realized when tests for common disorders with a genetic component are developed. Evidence is mounting that specific genes may predispose individuals to some forms of diabetes, heart disease, cancer, and mental illness. When these genes or genetic markers for these conditions are identified, predictive tests for these and other disorders may become available. Because genes are present in all body cells, tests can be applied using easily accessible tissues, such as blood, or in the case of prenatal diagnosis, through examination of fetal cells obtained through techniques such as amniocentesis. Thus, tests may be administered at any time prior to the onset of the disease and afford the possibility of therapeutic intervention to prevent the disease.

Several DNA-based tests for relatively rare genetic conditions are already available, but they rely on relatively sophisticated techniques, are difficult to interpret, and therefore are available only through a few specialized laboratories. The limitations of these tests pose considerable obstacles to their adoption by insurers.

There are two basic approaches to DNA-based testing for genetic disorders. The "linkage method" is being used to offer information to individuals within families in which certain genetic diseases have occurred. Genetic linkage tests are limited, because the exact location of the harmful gene is not known. Instead, the inheritance of gene markers (called "restriction fragment length polymorphisms" or RFLPs) is studied within families. For example, linkage analysis can be applied to Huntington's disease, an inherited disorder of the nervous system. These analyses require the cooperation of many family members (often including more than one generation) and are therefore not widely applicable. Even when the appropriate family members are available and the diagnosis of the genetic condition is well established, linkage tests may not be informative. Not all families have markers that can distinguish affected from non-affected individuals. Furthermore, since gene markers associated with the abnormal gene are examined and not necessarily the abnormal gene itself, erroneous conclusions are possible; for example, when genetic recombinations occur between the disease-causing gene and the marker.

When a disease-causing gene has been identified, direct tests have sometimes been developed that avoid many of the problems associated with linkage analyses. As these tests do not have to rely on the analysis of multiple family members, they may be amenable to population-wide screening. However, there are few conditions for which direct tests are currently available; and with the exception of sickle cell anemia, these conditions rarely occur. As more genes are identified that are associated with common disorders and as testing is simplified, genetic tests will be commercially developed. Until recently, one limitation on the use of genetic tests was the limited amount of DNA that was available for study, especially when analyzing prenatal specimens. Methods have now been developed in which enzymes are used to multiply the DNA sequences as much as 200,000 fold. These advances have simplified and accelerated the testing process and will allow more laboratories to conduct DNA-based genetic testing.

As of the beginning of 1988, there were no FDA-approved recombinant DNA tests for human genetic conditions. A limited number of these tests are available, however, through university genetic-counseling programs or through a few commercial laboratories.

Will insurance companies use genetic tests as part of their underwriting process? Genetic tests in their present state are impractical to administer, require considerable technical skills, may require analyses of multiple family members, are expensive to perform, and are currently available for only a small number of relatively rare diseases. Thus, it appears that in the near future, they will not be directly used in the insurance underwriting process. However, as genetic tests become increasingly available and used by clinicians, results from these tests will become part of the medical records of their patients. Applicants therefore will have to acknowledge their existence when filling out the medical history questionnaires, or insurers will become aware of these tests through attending physician's statements or copies of the applicant's medical records. Thus, insurers will occasionally have to factor these test results into their underwriting decisions. If tests are simplified and are shown to be predictive, they will in some cases be adopted by insurers.

One additional area of medical testing that could influence insurers' use of specific tests is the expected development of more self-testing for the home diagnostic products market. Insurers are always concerned over the problem of "adverse selection;" that is, applicants having knowledge of their medical conditions that is not made available to insurers, who then unknowingly approve these applications on the basis of incorrect risk assessments. (This has been of concern to insurers in those States where they have been prohibited from using the AIDS antibody test.)

There are now approximately 60 do-it-yourself kits available for a variety of conditions, ranging from pregnancy and ovulation to blood in the feces (an indicator of colon cancer). The largest home-testing market so far has been for therapeutic monitoring, such as monitoring by diabetics of their urine and blood sugar levels. There are currently few home diagnostic tests that prospective insurance applicants could use to determine whether they should obtain insurance in anticipation of having to seek medical care, but this is an area of obvious ongoing interest to insurers.

# CONCLUSIONS, ISSUES, AND OPTIONS

## Prospects for Increased Use of Medical Tests by Health Insurers and Employers

Truly new methods for detecting incipient or latent disease and even for predicting disease in healthy persons are being rapidly developed, particularly through recombinant DNA technology. Yet, many technological obstacles need to be overcome before their routine use and widescale applicability progress beyond hope into reality.

Even when these technologies become available, they may not be of practical use for insurers and employers for a number of reasons. First, there may not be a clear cause-and-effect relationship between abnormal findings on any single test and a specific disease, or a significant probability that a positive test would be predictive of developing the disease in the future. Current indicators of predispositions to disease seldom consist of a single factor but instead involve multiple factors whose interrelationships are still not well understood.

Second, tests will probably consist of two types: 1) less specific tests that identify a large number of persons with propensities to develop the index disease, and 2) more specific tests that can identify a subset of susceptible persons who will most likely develop a particular manifestation of the index disease. For example, tests may become available to identify persons who have a higher probability than average to develop cancer, or cardiovascular disease. Simultaneously, more specific tests may be found for identifying persons with a high probability of developing a specific type of cancer, or cardiovascular disease. In the first instance, insurers (and employers) will have to decide whether it is worth it to use a relatively nonspecific test that will be positive in large numbers of people, many (if not most) of whom will never develop the disease. In the second instance, many people would have to be tested in order to find the relative few with a high probability of developing disease. In either case, insurers (and employers) might find such testing not worth the effort when compared to how they currently deal with the probability that a certain number of their applicants (or employees) will develop these diseases. In other words, insurers already expect that some applicants whom they presently insure will develop these diseases, account for these diseases in their actuarial estimates when determining conditions of insurability and setting premium rates, and therefore might decide it not worth the added costs of testing for the amount of incremental information gained.

Third, while DNA technology holds promise in furthering predictive testing for common chronic diseases, despite rapid progress, it may still be years before such tests become simplified to the point that they can be used to screen large numbers of people in a cost-effective manner.

Fourth, from the viewpoint of clinical medicine, efforts in these areas are not merely directed at identifying persons with high probability (or certainty) of developing a particular disease. The ultimate aim is to find a treatment or cure, or even to prevent the disease. In the long run, many (or at least some) persons at risk for developing disease may avoid or have their illnesses reduced. This is especially true for genetic tests for common disorders where an interaction between environmental and genetic factors contributes to disease expression. Thus, persons currently at risk may eventually be more, not less, insurable.

While insurers might not find it cost-effective to use these tests themselves in screening prospective clients, if such tests are available to the medical community, insurers will still have to take these tests into account when making decisions on whether to insure an applicant, and if so, the terms under which that insurance will be issued. This will occur in two ways, both of which are already routinely used in evaluating insurance applicants. First, questions on such testing can be incorporated into the medical and family history questionnaire. Second, the use of such tests by the applicant's physician may be revealed when an attending physician's statement is requested or the applicant's medical record is reviewed.

Thus, not surprisingly, *the future impact of diagnostic and predictive medical tests on an applicant's insurability and on insurers' use of these tests will depend primarily on the infusion of these future tests into medical practice and not depend as much on the direct use of these tests by insurers in the underwriting process*. The regulatory implications are therefore quite different if insurers' knowledge of test results comes from the applicant's medical history and information provided by the applicant's physician, rather than from subjecting applicants directly to specific testing.

Will these tests have a significant impact on private insurers' willingness to continue to insure persons whose risks of developing disease can be predicted with fair certainty? Insurers are in the business of providing insurance, and they will continue to provide insurance to as many applicants as affordable. Thus, the impact on future private insurance availability might be limited; *but even such limited impacts might have major consequences for access to health care through private financing channels and the related impact on public health care expenditures, if private financing is reduced, with a concomitant increase in need for publicly financed health care*. Refinements in current methods of assessing risk that these future tests will provide will probably improve decisionmaking in current private health insurance practices. Certain risks currently declined or rated as substandard may in fact be insurable or upgraded to standard risks. The greater impact, however, is likely to occur in the following areas: declining to provide insurance to those at very high risk, charging higher premiums for higher-risk applicants, and issuing policies with certain diseases excluded from coverage. *These practices will aggravate what are already well-recognized shortcomings in our nation's health care system: 1) the problem of the uninsured and underinsured, and 2) inadequate catastrophic and long-term health care coverage*.

Employers are already engaging in practices to decrease their health care expenditures, such as self-insurance, increasing cost-sharing by their employees through larger deductible and co-insurance requirements, placing limits on the amount that will be expended on individual employees, controlling which providers can provide health care to their employees, or even ceasing or refusing to provide health care benefits to their employees.

*Employers may be more interested in using direct methods to control their employee health care costs than in using medical testing as a preemptive means to control expenditures for their employees' health care*. While some employers may be incorporating testing into health promotion programs, when employers are concerned over the health of their employees, that concern is primarily related to the impact of poor health on work productivity and the effect on other employees, not on employee health care costs. The focus of employers in testing is presently directed at drug abuse, and while health is a related concern, the primary impetus among employers to adopt drug testing is concern over poor performance, not poor health. Even AIDS antibody testing—when considered by employers for reasons other than uncertainty and fear—seems motivated more by the impact of AIDS on employee morale and customer perceptions than on the treatment costs of AIDS.

Will employers find predictive medical testing more attractive in the future? If they do so, whether their explicit motives include concern over employee health care expenditures would be beside the point, if such screening of applicants and employees nevertheless had the effect of shutting out many people from access to health care through employment-based health care plans.

## AIDS: a Unique Situation or a Paradigm for Future Actions?

What actions insurers and employers might take as new diagnostic and predictive medical tests become available are speculations. In contrast, accurate tests for identifying persons infected with the AIDS virus are already available, some decisions on their use have already been made, and other uses are under intense debate.

State legislatures have been most active in taking action on the use of tests to identify persons infected with the AIDS virus, and some of these laws have been directed at insurance and employment testing. The laws, however, have been quite variable. States such as Maine have prohibited insurers from inquiring whether the applicant has previously had an AIDS antibody test performed, but do not prohibit insurers from requesting such tests themselves. Wisconsin prohibited the use of tests for infections with the AIDS virus by insurers and employers but stipulated that tests that were found by the State epidemiologist to be accurate and reliable could be used by insurers. The State epidemiologist subsequently issued such a finding, so insurers—but not employers—can now test for AIDS antibodies in Wisconsin. The District of Columbia prohibited the use of AIDS testing by insurers but not by employers. New York attempted to prohibit use of the AIDS antibody test by insurers but has been denied by the courts. California prohibited the use of the AIDS antibody test by insurers and employers but did not prohibit other types of tests that might be used to indicate signs of AIDS. Commercial insurers in California therefore have been using a test that indicates impaired immune function—the T-cell test—to determine insurability of individual health insurance applicants. Anecdotal reports have since surfaced of applicants offering to show proof of negative testing results for AIDS antibodies when they have been refused insurance on the basis of an abnormal T-cell test, but insurers have declined to reconsider the application, citing the State prohibition in using the antibody test in determining insurability.

Insurers are concerned over prohibitions and limitations on inquiring about prior testing or conducting tests for infections with the AIDS virus because of the problem of adverse selection; that is, insuring persons already infected who apply for health insurance because of their known high probability of developing frank disease.

Are the approaches to insurance and AIDS that have been taken by some of the States unique? Prohibitions on refusing insurance for specific diseases or handicaps—and the complementary policy of requiring certain types of benefits to be provided—do have precedents. Some States have taken the position that persons with predispositions to some types of diseases or with some types of impairment, such as DES exposure (a drug that was used to prevent miscarriages but which subsequently was found to increase the risk of cervical cancer in female offspring of these women) or blindness, cannot be declined or charged higher premiums. And some types of benefits, such as treatment for alcoholism or drug addiction, are mandated by some States. *Issues concerning AIDS and private health insurance, therefore, may be more a matter of degree than novelty when compared to how other illnesses and benefits have been addressed in the past.*

Yet, there are novel aspects to the issue of insurance coverage for AIDS. It is a new disease, and its major routes of infection—sexual practices and intravenous drug use—predominantly affect young people. Employed young adults are the low-risk groups that subsidize the health care of other groups through their lesser need and use of health care services. Furthermore, by affecting young adults, the costs of caring for AIDS patients, while small relative to total health care costs, represent unanticipated additional costs. Furthermore, projections of the number of HIV-infected persons and AIDS cases even over the next decade are alarming. New treatments for AIDS are likely to increase health care costs for AIDs by prolonging the life of afflicted patients with expensive new drugs. These patients will probably continue to experience significant morbidity, thereby expanding their current needs for health and related support services.

Adding to the complexity of insurance coverage for HIV-infected persons is the knowledge that, at least for the next decade, the primary weapon against AIDS will not be found in the laboratory. The primary means to prevent further spread of HIV infections is, and will continue to be, education. The essential point of these educational messages is that infections with the AIDS virus are preventable, and that most persons can prevent infection through changes in, or avoidance of, known high-risk behaviors. (There are, of course, significant exceptions to the notion that risk is avoidable through individual behavior. These exceptions have included blood recipients, hemophiliacs, infants born to infected mothers, spouses of infected persons, and health care workers who have been accidentally stuck with contaminated needles.)

If an individual's destiny insofar as AIDS is concerned rests in his or her own behavior, why should exceptions to the health insurance risk assessment process be made for HIV-infected persons? A partial answer to this question is that insurance availability isn't the real issue, but that confidentiality of HIV antibody testing and other information that might identify an individual to be at risk for AIDS is the paramount issue, because of the profound discrimination and ostracism currently associated with AIDS. However, confidentiality is not the only issue. Clearly, persons at risk for becoming infected or who are already infected with the AIDS virus not only want their confidentiality maintained, they also want affordable access to health care.

*A fundamental issue is whether HIV-infected persons and AIDS patients have a special claim on health care resources over persons afflicted with other catastrophic illnesses*. One criticism of a special claim for AIDS is that such an approach is in direct conflict with the message that HIV infections are preventable through voluntary behavior, especially when those behaviors are, in the main, extremely sensitive and socially divisive subjects; such as, sexual practices and intravenous drug use. Even were these practices not involved, however, equity and cost considerations would be raised. *Since the extension of Medicare coverage in 1972 to include a specific disease, end stage renal disease (ESRD), and the attendant high costs of the ESRD program, costs alone have been an effective barrier against a disease-by-disease approach to health care for catastrophic illnesses.*

*Concerns over the accuracy and reliability of HIV antibody testing raise related and quite similar questions. The technical issues relating to AIDS antibody testing are important though not unique. They are highly visible manifestations of similar concerns that apply to all medical testing, for there are inherent limitations on the accuracy and reliability of all clinical laboratory tests.*

First, the abnormality or change in body function that is associated with the suspected disease or condition and which a particular test is designed to detect may not be present, even though the disease or condition is present. For example, in the test to detect occult blood in feces, a colon polyp or colon cancer may be present in the person tested, but there may not be blood in the feces at the time of testing. In HIV infections, an HIV antibody test may be performed during the early stages of infection when no or very small amounts of antibody are present.

Second, every test has its technical limitations; for example, there will always be some specimens in which the abnormality is in such low concentrations that the test either cannot detect the abnormality or cannot consistently and reliably detect it. Many tests have a "cutoff" point below which the results will be interpreted as negative. In general, when the cutoff point is lowered so that more test specimens will be interpreted as positive, more specimens without the abnormality will also be erroneously identified as being positive. In other words, when a test is made more "sensitive" so that fewer positive specimens will be missed ("false negatives") it will also be less "specific" and identify more negative specimens as positive ("false positives"). To illustrate, in AIDS antibody testing by blood banks, the ELISA screening test has been deliberately calibrated to have a very high sensitivity so that as many positive blood donations can be identified as possible. But this also means that most of the ELISA-positive blood specimens are not really positive, so testing of these positive specimens by a different method—the Western blot—is necessary. In 1987, American Red Cross rates for positive ELISA specimens were approximately 10 in 10,000. Upon Western blot testing, 8 of 10 specimens were negative, 1 was positive, and 1 was indeterminate. The "indeterminate" result points out that the Western blot test also has its limitations, with the indeterminate specimen probably representing early infection with the AIDS virus in most but not all cases. (Blood banks do not use any of the ELISA positive specimens, even when negative with Western blot testing.)

Third, it is axiomatic that the accuracy and reliability of tests when performed under everyday rather than ideal conditions will fall below their technically achievable levels. Moreover, there will be great variability among individual laboratories performing these tests. Variable accuracy occurs even when laboratories are tested and know they are being tested ("open testing"), and not surprisingly, laboratory performance will be worse when they do not know they are being tested ("blind testing"). In other words, there is a technical level of accuracy and reliability that is potentially achievable with each test, but most laboratories will not be able to achieve this potential even when they know they are being tested, and few laboratories will perform at optimal levels in their everyday practices.

Finally, even when the tests are performed with the same degree of accuracy across different populations, the probability that a positive test result will be correct will still decrease as the rate in which the abnormality is present in the tested population decreases. This is a simple mathematical fact. Suppose the sequence of tests—the ELISA screening test and the Western blot confirmatory test—will identify everyone with HIV antibodies in their blood and falsely identify only 1 in 100,000 persons as having HIV antibodies when they do not. In a population in which 10 percent had HIV antibodies, 10,000 of 100,000 persons tested would be correctly identified as positive. Among the remaining 90,000 antibody-negative persons, only 1 would be incorrectly identified as being HIV-antibody positive. Of the 10,001 positive tests, therefore, 99.99 percent of positive results would be correct. This "predictive value" of a positive test changes dramatically when a population with only a few HIV-antibody persons is tested. If only 10 in 100,000 were antibody positive, again, only 1 in the 99,990 HIV-antibody negative persons would test positive. However, in this case, there would only be a total of 11 positive results, and 10 of 11, or only 90.91 percent, would be correct. (Note that the predictive values would be even lower if the ability to detect all positive specimens was not assumed to be 100 percent.)

Tests with false positive rates of only 1 in 100,000 are extremely rare, if not unheard of outside of HIV antibody-testing. Blood bank testing and the Department of Defense's HIV-antibody testing program (and probably HORL, Inc., the major lab used by the insurance industry) may perform at this high level because of stringent quality controls over the laboratories conducting their tests, but it is not unreasonable to question whether the average lab conducting HIV-antibody testing can reach this level of accuracy. There is in fact evidence that the average lab not only has a much higher rate of false positives, but is also missing a number of HIV-antibody positive blood specimens.

HIV-antibody testing has received much scrutiny because of the controversies surrounding use of the test in underwriting life and health insurance for individuals and more importantly, in attempts to make testing mandatory among segments of the United States' population. Mandatory testing has been implemented in some areas, such as in the military, among immigrants, and for premarital testing in Illinois and Louisiana (and Texas, but the law there requires that infections in the State must reach a rate of 0.83 percent before premarital testing is initiated). However, the underlying technical issues concerning test accuracy, especially as actually conducted by laboratories, are common to all diagnostic and predictive testing. Periodically, questions have been raised over specific medical tests. For example, laboratory performance Pap testing for cervical and uterine cancer is currently under scrutiny, as is the accuracy and reliability of urine drug testing. Thus, the issues concerning HIV-antibody testing accuracy and reliability are common to all types of medical testing, although HIV-antibody testing deserves special scrutiny because of the societal consequences of being infected with the AIDS virus.

## Options Addressing the Use of Medical Tests

A wide range of initiatives has been and is being used to improve the accuracy and reliability of medical testing.

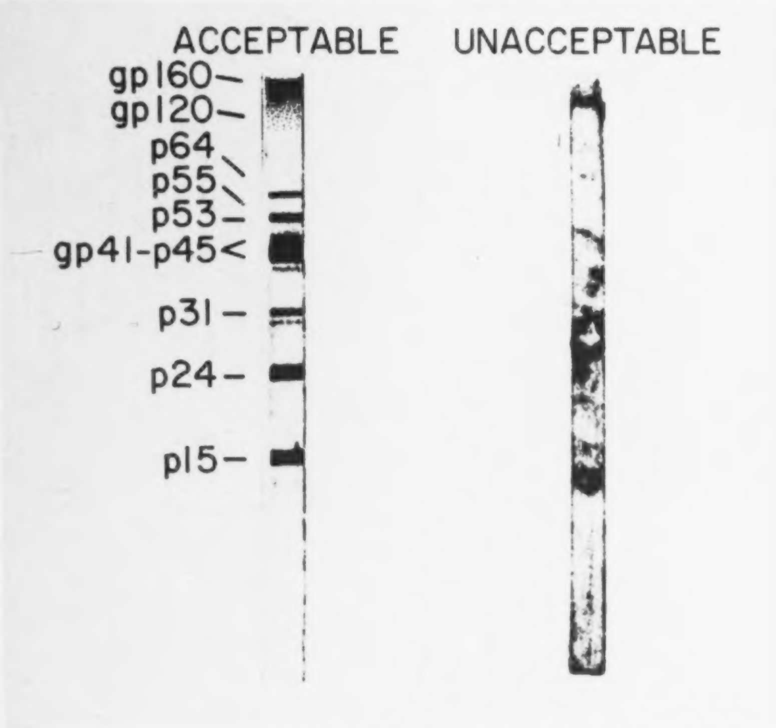
ACCEPTABLE
UNACCEPTABLE
gp160
gp120
p64
p55
p53
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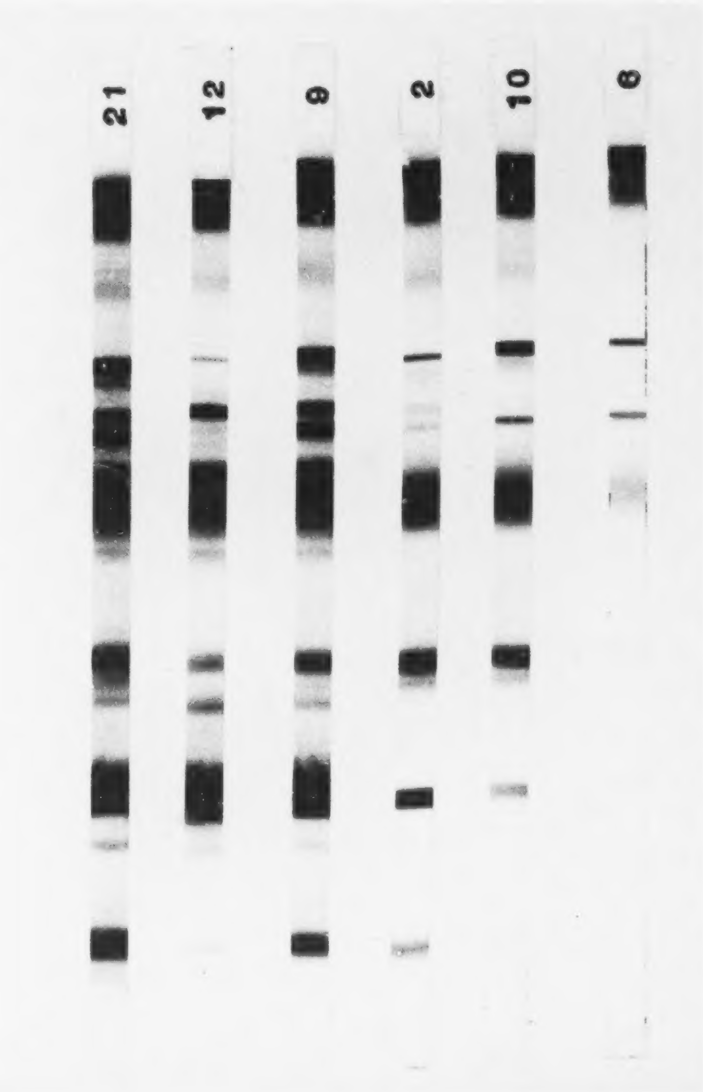
Photo credits: Department of Virus Diseases, Retrovirus Section, Walter Reed Army Institute of Research

(Above) Western blot preparation for HIV antibodies.



(Right) Examples of six strongly positive reactions.

First, laboratories have been provided "proficiency testing" services to assist them in maintaining and improving the accuracy of their performance. In proficiency testing, participating laboratories are sent prepared specimens (usually on a quarterly basis), which they then test and report back their findings. For example, the College of American Pathologists (CAP) has an extensive proficiency testing program in the various types of tests used in clinical medicine, as well as in AIDS antibody testing and drug testing (e.g., urine testing for cocaine, marijuana, opiates, etc.). In these programs, laboratories voluntarily participate for an annual fee and know when they are being tested—they receive test specimens at expected times and report their results back directly to the testing organizations. This is why these programs are called "open" proficiency testing.

In the 1970s, the Federal government, through the Centers for Disease Control (CDC), provided open proficiency testing services in a number of clinical testing areas. Most of these activities were phased out in the 1980s. However, because of the AIDS epidemic, CDC has now begun a proficiency testing program for AIDS antibody testing.

Second, the quality of medical testing can also be maintained by setting standards for laboratory personnel and testing procedures. Two methods are available for setting standards for laboratory personnel and performance: 1) set standards as part of direct licensing of laboratories, or 2) use standards as a necessary condition in order for labs to be reimbursed for services they perform.

Direct laboratory licensing has traditionally been in the purview of the States, but there is a great degree of variation in licensing. Few States regulate laboratory performance to any significant degree, and even within a State, monitoring can vary tremendously among the different types of tests—for example, clinical medicine testing versus drug screening testing. One variation in this approach is not "licensing" in the strict sense, but could be considered for specific types of testing. For example, New York prohibits commercial labs from performing AIDS antibody tests and specifies the types of labs that are allowed to perform these tests. Thus, designating the labs that are allowed to perform testing is a variation on standard setting.

In the Medicare program, laboratories must meet specified personnel and performance standards as a condition of participation (i.e., if they expect to be reimbursed for their services). For example, laboratory directors must meet certain educational/professional qualifications, and labs must participate and maintain a certain minimum score in specified proficiency testing programs (e.g., those of CAP).

Third, laboratory performance can be directly monitored. On-site inspections of labs are conducted by a few States whose laws and resources permit such activities, and similar inspections are periodically conducted by the Federal government on labs participating in Medicare. Criticisms over the frequency of these inspections and the number and types of labs subject to such inspections, however, are longstanding issues at both the State and Federal levels. Moreover, on-site inspections do not directly measure lab testing performance.

Participation in proficiency testing of the types offered by CAP is a method of monitoring laboratory performance, but this type of "open proficiency" monitoring only reflects at what level a lab is capable of performing. Open testing is not reflective of a lab's performance in everyday testing, and that level of performance can only be evaluated if the lab does not know it is being tested. Thus, "blind" testing has been instituted in some areas in which test samples have been inserted along with specimens received by the lab from one or more of its actual customers. In blind testing, labs know they are being tested, but do not know when they are being tested and which specimens are the test specimens. For example, in the Department of Defense's (DOD) extensive AIDS antibody testing program, DOD uses a monthly blind testing program to evaluate its contractor lab's performance (if the lab fails a certain amount of these tests, it does not get paid for that month). A similar program has been developed by the National Institute on Drug Abuse (NIDA) to monitor labs performing tests for the expanding urine drug testing program for selected Federal employees and contractors.

In blind testing of labs, implementing and maintaining the program are much more difficult than in open testing. In open testing, specimens can be sent directly to the lab, which then reports its results to the testing organization. In blind testing, arrangements must be made with actual customers of each lab; and the lab, because it cannot distinguish between real and test specimens, would be reporting the results to each customer. Thus, the administrative costs of a blind program would be much higher than in open testing.

If blind testing is used, a decision has to be made whether the Federal government would administer the program directly or by contracting it out, or whether arrangements would be made with existing, voluntary proficiency testing programs such as CAP to administer the program.

Finally, it must be remembered that it is the States, not the Federal government, that are most involved in regulating the quality of medical testing. Figures 1-2 to 1-5 summarize the extent of State regulation of laboratories that perform medical testing.

Congressional interest in the accuracy of laboratory testing has increased as a result of expanding urine drug testing programs, the continuing controversies over AIDS antibody testing, and more recently, concerns over the accuracy of medical testing in general. Several committees in both the House of Representatives and the Senate have held hearings on these issues (e.g., Committees on Energy and Commerce, Small Business, Post Office and Civil Service, and Government Operations in the House of Representatives; and Committees on Labor and Human Resources, Judiciary, and Governmental Affairs in the Senate). Thus, in addition to monitoring and proficiency testing of laboratories under contract to DOD to perform AIDS antibody testing and a similar program under NIDA for laboratories performing urine drug testing on designated Federal employees and contract personnel, current congressional scrutiny is focused on the laboratories performing medical testing in general, and especially those who participate in the Medicare program.

More recently, there also have been attempts to determine the appropriateness of using testing in specific circumstances, and to determine when the use of certain tests are justifiable. These approaches in fact have been used by some States. Thus, there are two options in addition to the more traditional means of maintaining and improving the accuracy and reliability of medical testing through standard setting and proficiency testing.

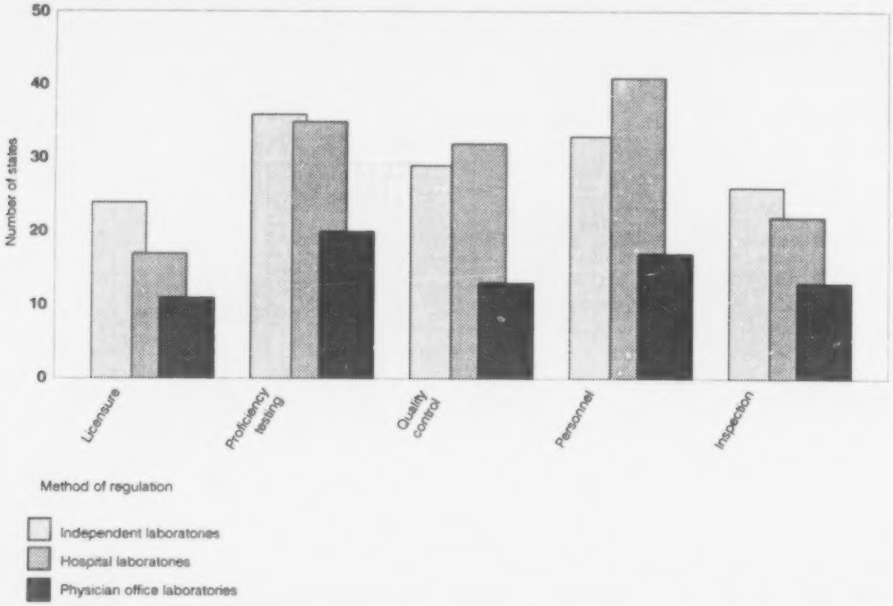
**Option 1: Allow use of a particular test only under specifically defined circumstances; for example, as some States have done for HIV-antibody testing for insurance and/or employment and for employment-based urine drug testing.**

This option would be applicable to specific tests and specific situations. An example is defining the circumstances in which drug testing of employees will be allowed. For example, in 1987, seven States passed such laws; six of these States limited drug testing to circumstances in which probable cause or reasonable suspicion existed. The other prominent example is the numerous variations among the States in defining when and under what circumstances (e.g., insurance underwriting, job applicant and employee testing) AIDS antibody testing is curtailed or prohibited.

While this option is not primarily based on an assessment of a test's accuracy and reliability, such considerations nevertheless are at least implicit in the reasoning. Recall the discussion above on the poorer predictive value (i.e., that a positive test result is truly positive) of a test when applied to populations with lower and lower rates of the index condition. Lower predictive value—and the increasing chances of a false positive identification—is among the reasons why caution is advised in screening low-use populations for drug use and low-risk populations for AIDS antibodies. Cost-effectiveness also becomes a consideration in screening low-use or low-risk populations, because everybody must be screened—and each positive on screening must be confirmed—in order to find the very few persons who are truly positive.

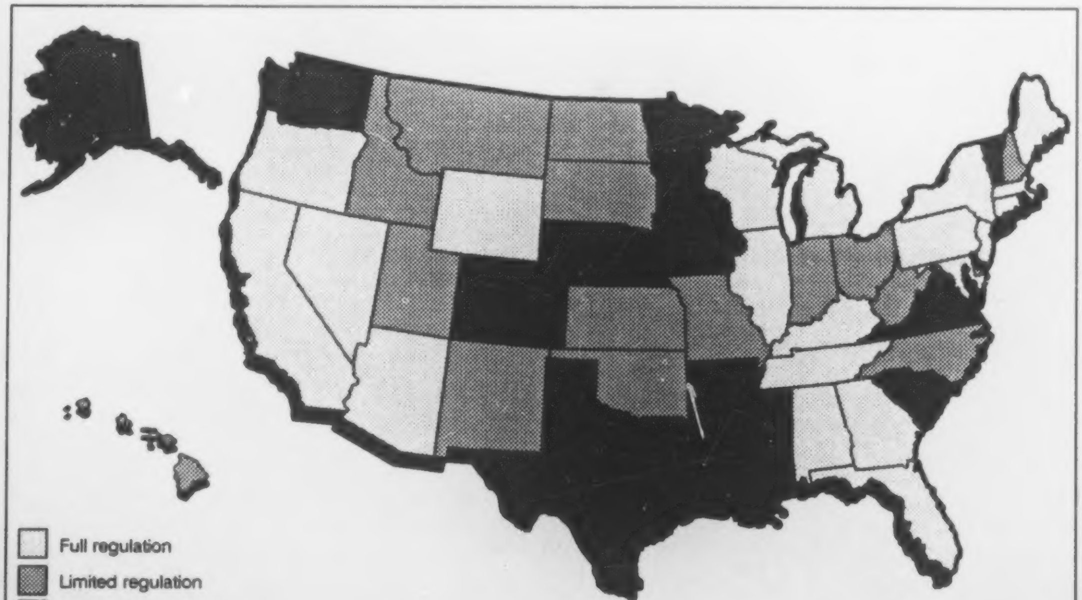
Testing does have the potential of helping those being tested. For example, one rationale for drug testing is to identify users in order to rehabilitate them. Tests could also be used to identify low-risk individuals to "exonerate" those with a positive family history for the disease (e.g., Huntington's disease).

Figure 1-2.—State Regulation of Clinical Laboratories, 1987



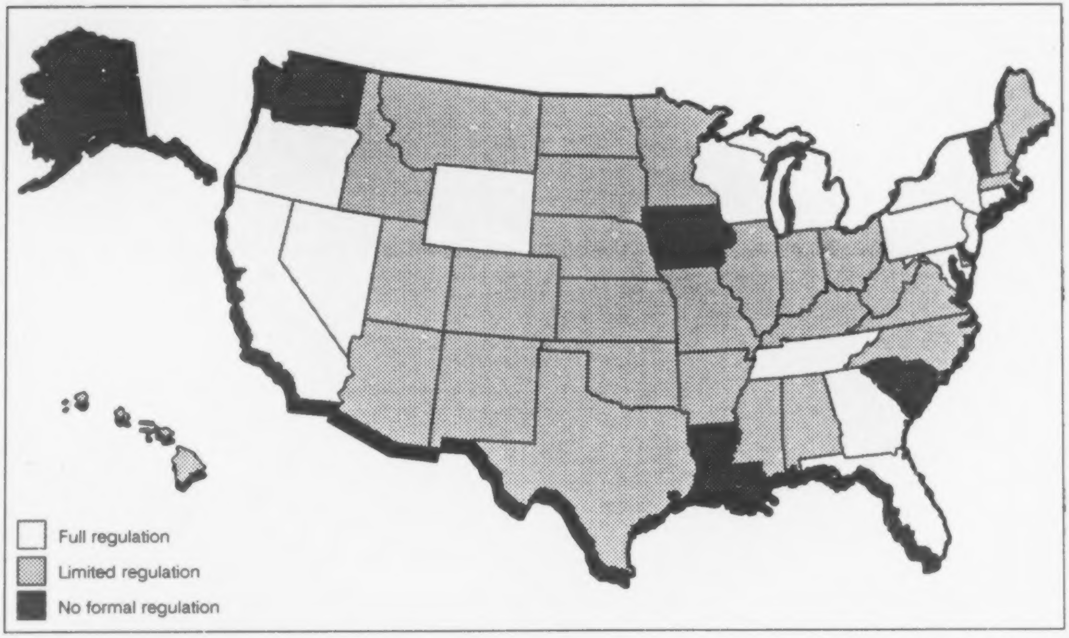
SOURCE: D.P. Baine, Associate Director, Human Resources Division, U.S. General Accounting Office, Washington, DC; information provided to The Honorable Ron Wyden, Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives, Feb. 29, 1988.

Figure 1-3.—State Regulation of Independent Laboratories, 1987



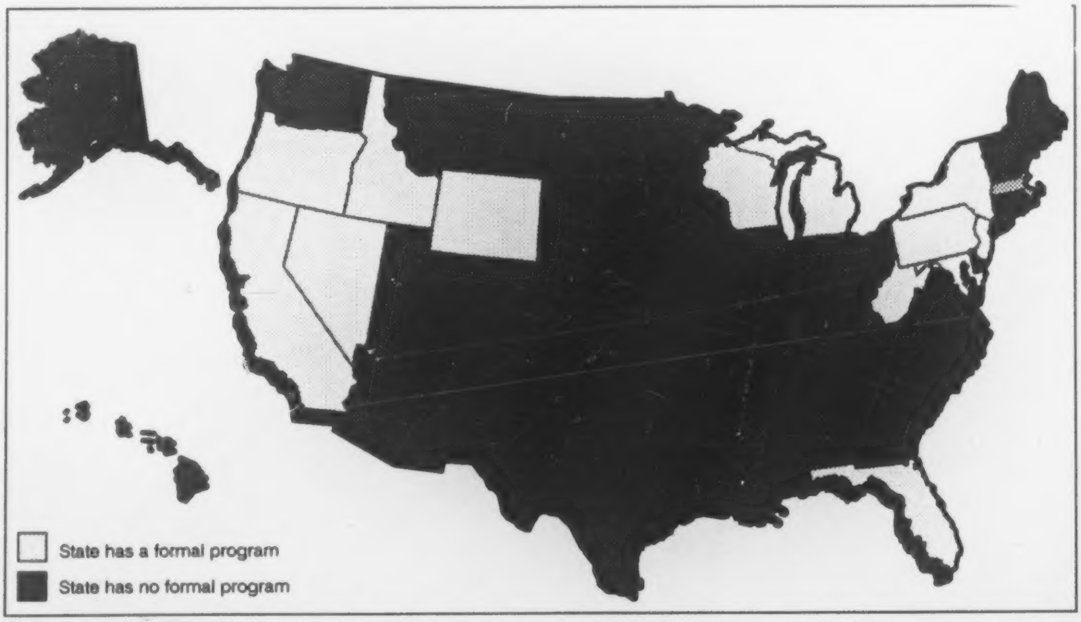
SOURCE: D.P. Baine, Associate Director, Human Resources Division, U.S. General Accounting Office, Washington, DC; information provided to The Honorable Ron Wyden, Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives, Feb. 29, 1988.

Figure 1-4.—State Regulation of Hospital Laboratories, 1987


Full regulation
Limited regulation
No formal regulation

SOURCE: D.P. Baine, Associate Director, Human Resources Division, U.S. General Accounting Office, Washington, DC; information provided to The Honorable Ron Wyden, Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives, Feb. 29, 1988.

Figure 1-5.—State Regulation of Physician's Office Laboratories, 1987


State has a formal program
State has no formal program

SOURCE: D.P. Baine, Associate Director, Human Resources Division, U.S. General Accounting Office, Washington, DC; information provided to The Honorable Ron Wyden, Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives, Feb. 29, 1988.

**Option 2: Limit the use of tests to tests that have been determined to be sufficiently accurate and reliable in the specific circumstances in which they are to be used.**

An available measure of a test's accuracy and reliability is licensing for commercial use by the Federal Food and Drug Administration (FDA); that is, FDA makes its licensing decision on a determination of test accuracy and reliability. However, FDA recommendations on when and how FDA-licensed products should be used are not necessarily followed. This is clearly the case in prescription drug use, where physicians often feel that once a drug is approved, they should be the ones to determine the circumstances of their use.

Some States have gone beyond FDA licensing and have expressed quite divergent views on this approach when applied to AIDS antibody testing. The Wisconsin legislature's approach was to require a finding by the State epidemiologist on whether a test was sufficiently accurate and reliable to use for insurance purposes (the State epidemiologist did make such a finding for the AIDS antibody test). In contrast, a proposed New York regulation was based on the conclusion that the presence of AIDS antibodies reflected infection with HIV and did not necessarily mean progression to frank AIDS, and thereby attempted to deny use of the test by insurers (initial court decisions have ruled against this prohibitory regulation). In California use of the AIDS antibody test is prohibited, but not other tests such as the less specific T-cell test.

Criteria that have been informally proposed by one insurer on the conditions that usually must be met before a medical test will be adopted by insurers are as follows:

- The test must supply information in addition to information otherwise available from other sources (e.g., from the medical history questionnaire).
- The disease tested for must have serious morbidity and/or mortality implications.
- The disease must be common enough to ensure that the test is predicitve and that costs of testing can be justified.
- The test must be predictive of disease (or absence of disease) and reliable.
- The test must be understood, accepted, and used by the medical profession.
- Laboratories must be able to readily perform the test.
- The test must be affordable and able to provide results quickly.
- The test must be risk-free.

Criteria such as these could be adopted by the National Association of Insurance Commissioners (NAIC) and issued as guidelines.

## Options on Strategies for Maintaining and Improving Access to Health Care

In the foregoing discussion on options to improve lab accuracy and reliability, each option can apply to lab testing of all types, or to specific types of testing (e.g., clinical medicine testing, AIDS antibody testing, drug testing) as circumstances and priorities dictate. An analogous situation exists in the area of financing of and access to health care. In developing strategies for maintaining and improving access to health care, one prominent issue is whether financing for AIDS care deserves a special, categorical approach or whether it has no special claim on the use of health care resources. However one comes out on these opposing policies, in general, the financing issues are similar for AIDS patients and patients suffering from other diseases. Thus, the policy choices are essentially the same for categorical and generic approaches, and how policymakers address AIDS versus other illnesses will depend on particular circumstances and priorities.

While the broader policy approaches are relatively easy to identify, the underlying issues are complex; and the specific policies that might be implemented are not only controversial, but each specific policy is also wrapped up in its own set of complexities and controversies.

Policymakers are well aware of the broad as well as the specific policy choices, and sustained efforts have been going on at Federal and State levels for at least the past 20 years. The financing needs of AIDS patients have only heightened the intensity of these efforts, but AIDS is not alone in contributing to the sense of urgency. Similar issues have arisen for patients in need of transplants or artificial organs and for technology-dependent children. Furthermore, the acute care needs of persons suffering from catastrophic illnesses is just the front side of the access and finance problem. Shortcomings in long-term care have long been recognized, which have gained added prominence by recent attention to Alzheimer's disease. The care of AIDS patients raises all of these issues.

Issues concerning health care access and financing include:

- the uninsured and underinsured;
- coverage for catastrophic illnesses;
- discontinuities or gaps in coverage (e.g., between acute and disability care);
- coverage and availability of long-term care; and
- the apportioning of financial responsibilities between private and public sector programs.

Given the breadth and complexity of these issues, it is clear that a list of options addressing these issues would be no less than an attempt to address every aspect of the United States' health delivery system. For example, there is wide agreement that long-term care needs are great, but these services have often not been developed and are often nonexistent even when financing is available. Thus, certain crucial elements of our health care delivery system are lacking or inadequate. Making financing available for these elements would assist in developing the necessary resources. Addressing areas in which the underlying services are in short supply or not available to begin with, however, makes for an extremely more difficult task than in addressing how available services might be made more accessible.

This report has a more narrow focus than the large issue of how health care can best be made available in the United States. The report addresses how medical and health-related laboratory tests are used and may be used in deciding whether specific individuals will be able to obtain health insurance, whether from insurance companies or through self-insured employers. Health insurance availability is currently high on Congress's agenda through such mechanisms as extensions of employment-based health insurance for ex-employees and efforts to require noncontributing employers to provide health benefits to their employees. While these efforts address the issue of inadequate or unavailable health insurance, they do not directly bear on the issue of medical testing. For example, a small firm may not provide health benefits to its employees, some of whom will have purchased health insurance policies individually. Or a small firm might have purchased health insurance for its employees, each of whom might have been individually evaluated by the health insurer (recall that small groups are often underwritten in the same manner as individuals). In the first case, requiring small firms to provide health insurance for their employees would obviate the need of individual employees to seek health insurance on their own. It would also ensure that all employees would be covered, not just those conscientious enough to purchase insurance. In the second case, there would be no difference if insurance coverage were mandated (except for the possibility of a change in the benefits covered by the insurance), because the employer already offered it.

*If we limit the analysis to those areas most affected by medical screening practices by health insurers and employers, and further limit the analysis to those areas of health care uniquely affected by these practices, then the principal issues involve the medically uninsurable population and coverage for catastrophic illnesses*. Those who fall in these categories will have severe deficiencies in access to long-term care as well as gaps between acute and long-term care coverage, but so will those currently with health insurance.

Finally, one of the issues leading to the congressional request for this report was the possible impact on public health care expenditures if private insurers declined to underwrite large numbers of applicants based on improved knowledge of latent and future illnesses. Insurers will in fact want to underwrite applicants as long as they can charge premium rates they consider reasonable. Thus, *the premise underlying the following options is that private insurance mechanisms will continue to be used to the extent possible for employed individuals (and their dependents)*.

**Option 3: Encourage the development of methods to provide insurance to high-risk individuals and those with catastrophic illnesses.**

Insurance pools for high-risk individuals and for catastrophic illnesses are not only undergoing experimentation among many States with both State and foundation (e.g., the Robert Wood Johnson Foundation) funds, but several States have already established pools, especially for high-risk individuals who are unable to obtain health insurance. Current State high-risk pools have large deductibles, high premiums, stop-loss provisions, and maximum lifetime benefits. Interest in such arrangements is high among many of the remaining States. However, experience with such pools is very limited. Direct costs to participating individuals are very high, yet expected and actual shortfalls between premiums and claims expenses are the rule. These shortfalls are financed either through mandatory contributions by insurers doing business in the State (which can be offset against their premium taxes), or by State general revenues.

Two of the principal issues concerning these emerging pool arrangements are: 1) the proliferation of pools with varying eligibility criteria and benefits, and 2) how shortfalls in revenues are to be covered.

*Option 3A: Amend the ERISA legislation so that self-insured groups can be required to help finance State high-risk insurance pools.*

Because of the ERISA exemption, self-insured health plans cannot be required to contribute to meet the revenue shortfall in those States with pools funded by mandatory contributions by insurers. Thus, insurers have called for Federal legislation to remove this exemption for self-insurers from ERISA. A limited version of this option is to require that employers pay the premiums of employees who would be eligible to join the State high-risk insurance pool. However, as premiums already fall short of covering the total expenses of these pool arrangements, this approach would increase revenue deficits as the number of participants increase, and such employers may have incentives to terminate insurance for their employers with high medical costs because of the lesser cost of transferring these employees to the State high-risk pool.

*Option 3B: Provide or require uniformity in eligibility, cost-sharing, and benefits for State high-risk pools.*

Although the provisions for these State pools are similar, there are varying eligibility requirements and benefits. On a voluntary basis, the NAIC could develop guidelines; or Federal legislation could specify the terms under which State pools function.

*Option 3C: Establish Federal high-risk pools in place of State pools.*

Federal legislation could also be considered to require States to establish high-risk and/or catastrophic illness pools, or to establish a Federal program along the lines of the catastrophic insurance proposals that have been periodically considered in the Congress.

**Option 4: Use incentives and subsidies to provide (and maintain) private health insurance for the uninsured and persons at high risk or with catastrophic illnesses.**

*Option 4A: Create larger risk pools for smaller firms.*

By creating larger risk pools, premiums can be lowered for small employers who band together and act as a large employer. Multiple Employer Trusts (METs) have not lived up to expectations along this line, but it is not clear why this is the case. Larger risk pools for small firms could also be created through approaches similar to the Federal unemployment insurance tax.

*Option 4B: Use public funds to subsidize participation in private insurance arrangements for high-risk individuals rather than transferring such persons to public assistance programs.*

Direct costs to public programs, as well as the administrative costs associated with switching from one claims processor (private) to another (public), may make public programs that subsidize all or part of private insurance premiums before these persons' insurance policies lapse more cost effective than leaving such persons to exhaust their resources and eventually become eligible for Medicaid (or Medicare). Another possibility would be to subsidize or share the costs of premium contributions to State high-risk pools for persons who might otherwise become eligible for Medicaid or Medicare.

*Option 4C: Provide "gap" insurance through further extensions of employment-based coverage and use of Medicare stop-loss measures for those persons in danger of losing private insurance.*

Little is known about the extent to which persons with private insurance eventually lose coverage because of the duration of their catastrophic illnesses, either through inability to continue paying premiums, exceeding their coverage limits, and/or nonrenewal of their insurance policies. Anecdotes abound of these occurrences among AIDS patients and their eventual eligibility for Supplemental Security Income and Medicaid, and of persons who become medically indigent but not quite eligible for Medicaid and must continue treatment through other public (e.g., county, municipal) and private (e.g., unreimbursed) resources.

Under the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, non-government and nonreligious employers with more than 20 employees must give employees who leave the option of remaining in the employee group for health insurance for up to 18 months, as long as the employee pays the employer and employee shares of the premium, plus no more than another 2 percent of the total premium.

For those with illnesses and disabilities that would make them eligible for Medicare coverage, extension of COBRA could cover the period between loss of private health insurance and enrollment into the Medicare program. As there is a preliminary 6-month waiting period before Medicare's 2-year formal waiting period (to establish permanent disability) begins, thereby resulting in an actual waiting period of 30 months, COBRA benefits could be extended to 30 months. Alternatively, COBRA benefits could be extended to 24 months while concomitantly reducing the formal Medicare waiting period to 18 months. This combination of options, of course, would only be available to persons who could meet current Medicare requirements for total and permanent disability, or who would meet Medicare age eligibility in the interim period.

**Option 5: Ease eligibility requirements for Medicare and/or Medicaid.**

*Option 5A: Reduce the Medicare waiting period and/or change the disability definition.*

Changes in the Medicare program have been suggested as a way, for example, of financing the health care of AIDS patients. Suggested changes include reducing or eliminating the waiting period, and/or changing the definition of total and permanent disability, such as through disease-specific categories as is currently the case for end-stage renal disease (ESRD). However, as discussed previously, this approach brings up the issue of a disease-by-disease versus generic approach to the disability provisions of Medicare, and in the case of AIDS, the issue of favoring AIDS patients over persons with other catastrophic illnesses.

*Option 5B: Expand Medicaid eligibility by raising eligibility ceilings.*

If Medicaid eligibility were expanded to all people below some fraction of the poverty level, it would particularly help the very poor in States that currently have low income eligibility ceilings, as well as IV drug users and homosexual men with AIDS who do not meet current categorical eligibility criteria for Medicaid (e.g., custody of children) but who are below the poverty level.

*Option 5C: Allow selected buy-ins into the Medicaid program.*

Another use of Medicaid to reduce the pool of uninsured is to allow people who are categorically ineligible for Medicaid but who have incomes below some multiple of the poverty level (e.g., 75 percent or 150 percent of the poverty level) to buy into Medicaid on a sliding-scale fee basis. The extent of the Medicaid premium that is subsidized would determine participation. If only a small fraction of the premium is subsized, few of the poor would be likely to buy in.

**Option 6: Supplement Federal payments or provide special grants to areas and/or institutions highly affected by catastrophic illnesses.**

The impact of catastrophic illnesses may fall unevenly on different geographic areas and on different institutions in a geographic area. This has been the pattern with AIDS, and because of the programs of care that have been developed (e.g., San Francisco) or the types of patients that have been affected (e.g., drug abusers in New York City), specific areas and specific institutions within those areas may bear a burden out-of-proportion to what would be expected if only permanent residents of those areas sought care. Thus, a double burden might be imposed: first, on the patients, for whom financial resources will be less available because of the numbers of similar patients seeking care, and second, on the providers of care, because of the additional resources that are needed to provide the extra care. Many, if not most, of these patients will have exhausted their private resources or will already be supported by public programs.

Supplements could be provided on both individual and institutional bases; that is, through diagnosis-specific supplements in the Medicaid program, and direct grants to institutions—especially public institutions—with disproportionate shares of catastrophically ill patients. In the current Medicaid waiver program, expenditures cannot exceed levels currently provided for traditional services. Granting of supplemental funds could include—or be used exclusively for—development of alternative sites of care and new types of services and thus be used to augment the current Medicaid waiver program.

These options are summarized in table 1-3. Table 1-4 summarizes State laws and regulations concerning HIV antibody testing by insurers and by employers. Table 1-5 summarizes health insurance legislation before the Congress as of April 1988, concerning coverage for the uninsured and provisions for high-risk individuals (excluding elderly groups).

**Table 1-3.—Major Issues and Related Options**

| Use of medical tests | Access to health care |
|---|---|
| ***Current situation:***<br>Few States regulate laboratory performance to any significant degree. In the Medicare program laboratories must meet specified personnel and performance standards as a condition of participation. Current congressional scrutiny is focused on the performance of laboratory testing in general; i.e., clinical medicine testing, HIV antibody testing, and urine testing for illegal drug use. There have been State actions determining when the use of certain tests are justifiable and the circumstances under which it is appropriate to use certain tests (e.g., HIV antibody tests). | ***Current issues:***<br>Issues concerning health care access and financing include: 1) the uninsured and underinsured, 2) coverage for catastrophic illnesses, 3) discontinuities or gaps in coverage (e.g. between acute and disability care), 4) coverage and availability of long term care, and 5) the apportioning of financial responsibilities between private and public sector programs. In addressing these issues, private health insurance mechanisms will continue to be used to the extent possible for employed individuals and their dependents, and there is great resistance to a disease-specific approach for coverage of catastrophic illnesses. |
| ***OTA options:***<br>#1: Allow use of a particular test only under specifically defined circumstances; for example, as some States have done for HIV-antibody testing for insurance and/or employment and for employment-based urine drug testing.<br>#2: Limit the use of tests to those that have been determined to be sufficiently accurate and reliable in the specific circumstances in which they are to be used. | ***OTA options:***<br>#3: Encourage the development of methods to provide insurance to high-risk individuals and those with catastrophic illnesses.<br>#3A: Amend the ERISA legislation so that self-insured groups can be required to help finance State high-risk insurance pools.<br>#3B: Provide or require uniformity in eligibility, cost-sharing, and benefits for State high-risk pools.<br>#3C: Establish Federal high-risk pools in place of State pools.<br>#4: Use incentives and subsidies to provide (and maintain) private health insurance for the uninsured and persons at high risk or with catastrophic illnesses.<br>#4A: Create larger risk pools for smaller firms.<br>#4B: Use public funds to subsidize participation in private insurance arrangements for high-risk individuals rather than transferring such persons to public assistance programs. |

## Table 1-3.—Major Issues and Related Options—Continued

| Use of medical tests | Access to health care |
|---|---|
|  | #4C: Provide "gap" insurance through further extensions of employment-based coverage and use of Medicare stop-loss measures for those persons in danger of losing private insurance.<br>#5: Ease eligibility requirements for Medicare and/or Medicaid.<br>#5A: Reduce the Medicare waiting period and/or change the disability definition.<br>#5B: Expand Medicaid eligibility by raising income eligibility ceilings.<br>#5C: Allow selected buy-ins into the Medicaid program.<br>#6: Supplement Federal payments or provide special grants to areas and/or institutions highly affected by catastrophic illnesses. |

SOURCE: Office of Technology Assessment, 1988.

## Table 1-4.—State Laws and Regulations Concerning HIV Antibody Testing by Health Insurers (as of April 1988)

***Arizona:***

*Insurance department action*—A circular letter contains underwriting guidelines implemented to protect against unfair discrimination. No questions may be asked regarding lifestyle, sexual preference, receipt of blood transfusion, previous AIDS-related tests or exposure. The guidelines prohibit the sale of policies containing a general exclusion for AIDS and AIDS-related claims. Informed consent required.

***California:***

*Legislation*—Prohibits using the results of blood tests which detect antibodies for AIDS to determine insurability, including the ELISA and Western Blot. Tests for deficiency of immune status, such as T-cell tests, are not prohibited. Prohibits testing without written consent.

*Insurance department action*—A regulation prohibits discrimination based on sexual orientation. Insurers may not ask about prior blood tests or results.

***Colorado:***

*Legislation*—Prohibits testing for HIV infection without consent of the individual.

*Insurance department action*—A regulation includes the NAIC guidelines. Testing is permitted if the three-test protocol is followed (ELISA-ELISA-Western blot). Policies cannot exclude or limit coverage for AIDS-related treatment.

***Connecticut:***

*Insurance department action*—No questions about AIDS testing may be asked, but insurers are not prohibited from testing.

***Delaware:***

*Insurance department action*—A regulation requires written consent in order for an applicant to be tested and outlines the types of questions allowed. The NAIC guidelines have been issued as a bulletin.

***District of Columbia:***

*Legislation*—Prohibits insurers from requiring or requesting anyone to reveal if he has taken a test to screen for AIDS antibodies and prohibits insurers from refusing to insure an individual or limiting or changing coverage in any way because he has tested positive on any test to screen for AIDS antibodies. The statute also prohibits using factors such as occupation or sexual orientation to determine insurability. Testing is, however, permitted where the applicant exhibits symptoms of AIDS. Insurers can deny coverage to an applicant with AIDS but not someone with HIV antibodies and no symptoms of the disease. Informed consent required.

***Florida:***

*Legislation*—Test results from serologic tests conducted under a declaration by the State Department of Health and Rehabilitation Services are prohibited from being used to determine insurability.

*Insurance department action*—NAIC guidelines adopted. A regulation requires written consent before any testing procedure. Coverage may not be written containing an exclusion for a specific disease.

***Hawaii:***

*Legislation*—Health care providers are forbidden from testing a person for the presence of HIV antibodies without written informed consent. The Unfair Trade Practices Law forbids insurers to refuse to insure someone, or limit his coverage, because he has previously had an HIV test, or because he refuses to release information related to a prior test. The insurer may, however, get permission from the applicant and have a test done in a manner which satisfies the requirement of the commissioner.

***Illinois:***

*Legislation*—Any insurance company must have written consent before testing applicants for HIV antibodies. No insurer may discriminate in the availability of insurance on the basis of sexual preference, or apply different rates on the basis of sexual preference unless the rating classification is based on expected claims, costs, and expenses.

***Indiana:***

*Insurance department action*—A pending regulation includes the NAIC guidelines; however, testing is permitted if testing requirements and protocol are followed.

### Table 1-4.—State Laws and Regulations Concerning HIV Antibody Testing by Health Insurers (as of April 1988)—Continued

***Iowa:***

*Insurance department action*—The NAIC guidelines have been adopted; testing is permitted.

***Kansas:***

*Insurance department action*—A temporary regulation defines how many and what types of tests must be completed and how they should be disclosed. Types of questions which may be asked also specified. Informed consent required.

***Maine:***

*Legislation*—No insurer may request any person to reveal whether the person has obtained a test for the presence of antibodies to the AIDS virus prior to an application for insurance coverage. Prohibits testing without informed consent.

***Maryland:***

*Insurance department action*—Guidelines issued specify types of tests to use and restrict questions on the application to those that elicit specific medical information rather than lifestyle or sexual orientation inferences. Informed consent required.

***Massachusetts:***

*Legislation*—Prohibits health care providers from testing without informed consent.

*Insurance department action*—A regulation prohibits requiring or requesting health insurance applicants to take any HIV-related test. Includes a nondiscrimination provision which prohibits underwriting based on factors such as lifestyle or living arrangements. Implementation is currently stayed by court order. A regulation states that no insurer may ask a proposed insured about a prior HIV-related test or the result and are prohibited from considering any such information in determining insurability.

***New Jersey:***

*Insurance department action*—A bulletin prohibits testing for group health insurance yet permits it for individual coverage if it is "medically justified". Blood testing may not be requested based on information about the applicant's lifestyle and, when used, must be ELISA-ELISA-Western blot series. Stipulation on type of question permitted referring to AIDS tests. Informed consent required.

***New York:***

*Insurance department action*—A regulation prohibits denying health insurance to an individual based on results of a test used to determine HIV antibody status. Insurers may not request an applicant to submit to a test, or ask whether he has taken such a test, or consider the results of any previously administered test. Implementation was prohibited by court order.

***Oregon:***

*Legislation*—Insurance organizations must obtain written consent before testing for HIV antibodies.

*Insurance department action*—Temporary rules adopted contain the NAIC underwriting guidelines. Three-test protocol required (ELISA-ELISA-Western blot). Policies must cover HIV infection. No general question regarding taking an HIV test is permitted, though the direct question asking if the applicant has ever tested positive for HIV is allowed.

***Rhode Island:***

*Insurance department action*—A proposed regulation prohibits testing for group policies, but permits it for individual policies. Also includes the NAIC guidelines.

***South Dakota:***

*Insurance department action*—The NAIC guidelines have been adopted; testing is permitted. Informed consent required.

***Texas:***

*Legislation*—Prohibits testing for HIV infection with specified exceptions.

*Insurance department action*—A proposed regulation clarifies the law, allows testing, and contains testing protocol (ELISA-ELISA-Western blot). A proposed regulation prohibits discrimination and contains the NAIC guidelines. Informed consent required.

***Washington:***

*Insurance department action*—A regulation permits testing only on a nondiscriminatory basis, and requires a test with high degree of accuracy before an applicant may be declined or rated substandard. Ambiguous or misleading questions on the application are prohibited.

***West Virginia:***

*Legislation*—Prohibits insurers from canceling or not renewing policies because of a diagnosis or treatment of AIDS.

***Wisconsin:***

*Legislation*—Prohibits insurers from requiring HIV tests or using test results in determining individual health insurance rates unless the tests are deemed medically significant by the State epidemiologist and sufficiently reliable by the Commissioner of Insurance. Testing for group coverage prohibited.

*Insurance department action*—A regulation accepts the approval of the ELISA/ELISA/Western blot series for HIV testing from the State epidemiologist. Another regulation prohibits discrimination because of sexual orientation. Informed consent required. NAIC guidelines adopted.

SOURCE: Office of Technology Assessment, 1988.

**Table 1-5.—Health Insurance Legislation Before the 100th Congress (as of April 1988) Concerning Coverage for the Uninsured and Provisions for High-Risk Individuals (Excluding Medicare-Specific Legislation)**

***Legislation for High Risk Individuals:***

S. 24/H.R. 276—Amends the Social Security Act to eliminate, for five years, the requirement that an individual be entitled to disability benefits for at least 24 consecutive months in order to qualify for hospital insurance benefits for those with AIDS.

S. 1634—*Access to Health Insurance for Medically Uninsurable Individuals Act of 1987*—Encourages States to set up pooling mechanisms through a ten million dollar grant program to provide health insurance for medically uninsurable individuals. States will receive funds based on their proportionate share of the national population to be used toward establishing health insurance risk pools. The States themselves would be responsible for financing, design, and subsidization of the pools.

H.R. 406—*National Catastrophic Illness Protection Act of 1987*—Amends the Social Security Act to establish a national catastrophic illness insurance program under which the Federal Government, working in conjunction with State insurance authorities and the private insurance industry, will make adequate health protection available to all Americans at reasonable cost. The program will involve the creation of State-wide plans providing extended health insurance with the Federal Government reinsuring insurers and pools of insurers offering such insurance.

H.R. 1182—*Health Services Act of 1987*—Amends the Social Security Act to establish a public/private program to provide health services to the medically uninsured not eligible for Medicaid. The program will provide benefits to residents of a State where there exists a Statewide Pooling Corporation. A Federal Health Trust Fund will be established to pay direct grants to such corporations.

H.R. 2300—*Catastrophic Illness Expense Protection Amendments of 1987*—Amends the Internal Revenue Code to deny employers an income tax deduction for group health plan expenses unless the plan provides full catastrophic coverage for physician and hospital services provided to a covered employee or family member during any period within the plan year after out-of-pocket expenses for certain medical services exceed $2,000 ($3500 for family coverage) and does not cancel or differentiate in coverage except in cases of failure to pay premiums due.

H.R. 3766—*Comprehensive Health Care Improvement Act of 1987*—A bill to provide for certification and require the offering of qualified health plans, to provide Federal assistance to States to establish a program of assistance for low-income persons to purchase comprehensive health insurance, and a program for coverage of catastrophic health care expenses.

***Legislation For Those With No Health Insurance Coverage:***

S. 177—*Health Care for the Uninsured Act of 1987*—Permits States to establish health care pools to provide health care services to all uninsured individuals and to share among all hospitals in the State the costs of the uncompensated care. Requires the implementation of the health care pool at the Federal level where a State does not establish such a program or receive a waiver form the Secretary of Health and Human Services. Each uninsured individual seeking coverage through the pool will pay a premium based on the individual's family income.

S. 1139/H.R. 3580—*MedAmerica Act of 1987*—Amends the Social Security Act to give States the option of extending coverage to:

- individuals whose family income does not exceed an income level established by the State at or below 200 percent of the Federal poverty level;
- those who are unable to obtain health insurance coverage from another source by reason of a preexisting medical condition;
- those who have exhausted some or all of the benefits under their health insurance policy; and
- those whose employer employs no more than 25 individuals and is unable to provide adequate health insurance coverage for such individuals at a reasonable cost.

S. 1265/H.R. 2508—*Minimum Health Benefits for All Workers Act of 1987*—Amends the Public Health Service Act to require each employer to enroll each of its employees and their families in a health benefit plan. Makes State employers which do not so enroll their employees and their families ineligible to receive grants, contracts, loans, or loan guarantees under such Act. Amends Fair Labor Standards Act of 1938 and Employee Retirement Income Security Act of 1974 to require each employer to enroll each of its employees and their families in a health benefit plan. Amends ERISA regarding supersedure of State laws relating to contracts or policies of insurance issued to or under a health benefit plan under this Act.

S. 1370—Amends the Internal Revenue Code to increase from 25 to 80 percent the income tax deduction for the health insurance costs of a self-employed individual.

S. 1386—Amends the Internal Revenue Code to increase the income tax deduction for the amount of health insurance costs of a self-employed individuals from 25 to 100 percent. Permits income tax deductions for self-employed individuals in the amount of their contributions to group health plans that are not self-insured and that provide medical benefits to employees.

H.R. 200—*USHealth Program Act*—Amends the Social Security Act to ensure access for all Americans to quality health care, regardless of age or disability, while containing the costs of the health care system.

H.R. 955—*Health Care Savings Act of 1987*—Amends the Internal Revenue Code to permit individuals and employers to contribute to health care savings accounts. Limits the amount which may be contributed to a health care savings account each year to no greater than the combined amount of employee and employer hospital insurance payroll tax paid during that year. The employee and the employer will each receive a 60 percent tax credit for their respective portion of their hospital insurance payroll tax paid.

H.R. 2696—*Universal Health Insurance Act of 1987*—Amends the Social Security Act to make health insurance widely available to all U.S. citizens. Each enrollee shall pay a premium equal to six percent of the sum of the amount of an individual's verified income and the amount of the individual's net assets.

H.R. 3065—(no title)—Amends the Internal Revenue Code provisions relating to the income tax deduction for the health insurance costs of self-employed individuals to increase from 25 to 100 percent the allowable deduction and make the deduction permanent.

H.R. 3766—*Comprehensive Health Care Improvement Act of 1987*—See above.

SOURCE: Office of Technology Assessment, 1988.

## Chapter 2

# Private Health Insurance: Background and OTA Survey

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Chapter 2

# Private Health Insurance: Background and OTA Survey

## INTRODUCTION

The majority of people in the United States under the age of 65 who are protected by private health benefit programs are covered through some type of group plan, usually sponsored by an employer. In group insurance, the underwriting unit is the group itself, and not the individual members of the group. The overwhelming majority of persons with private health coverage in the United States are protected by some type of group health benefits program.[1] Thus, with some exceptions coverage is ordinarily offered without medical examination or evidence of individual insurability. Individuals and small groups, however, are often "medically underwritten," meaning that their health history and current health status directly bear on whether they will be insured.

In a private, voluntary health insurance system, not all applicants for insurance meet the underwriting criteria established by insurers. Thus, the marketplace does not meet the insurance needs of all individuals who want insurance. Those who are already ill or who, in the judgment of the insurers, present a very great risk for claims, may be denied insurance altogether. Thus, serious policy problems are posed for dealing with the needs of the uninsured in general, and the high-risk uninsured in particular.

In this chapter the following areas are examined:

- a review of the basic principles of health insurance and the differences between group and individual underwriting;
- an examination of the regulatory framework for health insurance, and brief discussions of applicable State and Federal laws;
- a discussion of the current health benefits marketplace; and
- a description of the role of medical tests in the underwriting process, including the use of AIDS antibody testing by insurers.

## GROUP V. INDIVIDUAL HEALTH INSURANCE

The purpose of insurance is to minimize financial losses that may arise from unexpected events. Insurance operates by spreading risks so that many individuals who could have a loss, but don't, help pay for the losses of the few that do sustain loss. Insurers are in the business of spreading or pooling risks and, in exchange for premiums, agree to pay all or part of some definable loss. Insurance also works on the principle that there must be uncertainty that a loss will occur, and that the loss is beyond the control of the insured. Thus, insurance is not written for losses that are already occurring—"you can't buy fire insurance on a burning building." In such cases, the insurer would have to charge the full amount of the loss the insurer agreed to cover, plus additional charges for the insurer's services.

Insurers establish the costs of insurance (i.e., premiums) on the basis of an assessment of the potential losses that they expect to incur. To accomplish this, they employ the mathematical principles of probability and the law of large numbers (125). The ability to make reasonable predictions about expected losses improves as the number of observations of the events leading to losses increases.

The size of a potential loss is another factor in insurance. Potential losses should ordinarily be of such a large magnitude that their occurrence has a significant financial impact on the insured. Budgetable expenses and small losses are generally not insured, because the administrative costs of such insurance would be very high relative to claims paid. The insurer would have to collect premiums not only to cover the small losses but also to pay the expenses of handling many claims transactions. The most administratively efficient forms of insurance, therefore, cover only potentially large losses that seldom occur and that seriously affect the financial position of the insured when they do occur. Measured by these criteria, some forms of insurance are less efficient in their design (e.g., first dollar coverage or no deductible) than other forms.

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[1] The Health Insurance Association of America (HIAA) estimates that in 1985 only 11 percent of commercial health insurance policies covering those under age 65 were for individuals and their family members (66).

Finally, private insurance operates on the principle that the costs of insurance generally should be proportional to the risks involved. Individuals applying for private insurance whose potential losses are large are expected to pay higher premiums than those whose potential losses are likely to be less.

The term "health insurance" broadly includes various types of insurance—such as accident insurance, disability income insurance, medical expense insurance, and accidental death and dismemberment insurance—that are designed to reimburse or indemnify individuals or families for the costs of medical care arising from illness or injuries.

## Distinguishing Features of Individual v. Group Insurance

Although individual and group health insurance plans provide protection against similar types of medical expenses they are, in a sense, fundamentally different types of insurance. Understanding the differences is important in judging how each type of insurance responds to the needs of the insured, including those who are at high risk.

### The Contract

An individual health insurance contract is one made by an insurer with an individual applicant, called a "policyholder" or "subscriber," and normally covers that individual or, in some cases, the individual and his or her dependents. A group insurance contract is made with the sponsor of the group coverage—usually an employer—and covers a group of persons (and in some cases, their dependents) identified as individuals by reference to the group. The group sponsor, not the members of the group, is the insured party. Group insurance contracts are, as a rule, continuous in nature and ordinarily continue beyond the lifetime or membership in the group of any of its participants. Though some terminations do occur, most employers and other groups provide health insurance continually as an ongoing part of their regular fringe benefit programs.

### Underwriting Differences

Among the most important of the differences between individual and group insurance is the matter of risk selection, or underwriting. Underwriting refers to the processes used by insurers to select, classify, rate, and accept or deny risks.[2]

With some exceptions (such as in the case of small groups), group insurance is generally issued without medical examination or other evidence of insurability. Group underwriters are usually interested only in whether the group as a whole can be insured. In a large group of employed persons (and their dependents), it is presumed that the overall risk for the entire group is close to average and that there are relatively few individuals who have health needs of such severity or frequency that they would be uninsurable or substandard risks for individual insurance coverage. In other words, the variation in average risk among group contracts—where the group size is reasonably large—is likely to be small.

In contrast, applicants for individual insurance are not part of a well-defined, homogeneous, and generally healthy group. Because of the potentially great differences in the health status and potential risks presented to insurers by individual applicants, insurers evaluate individuals by using quite different criteria than are used in underwriting groups. Thus, "medical underwriting" is customarily used by most insurers to determine whether and under what terms individual insurance coverage will be approved.

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[2] The term "underwriting" is sometimes used in a narrower sense to refer simply to the process by which an insurer accepts or rejects an applicant for insurance.

### Adverse Selection

"Adverse selection" refers to the situation whereby, in the absence of any controls, persons who seek to obtain insurance will tend to be those who will use it the most, that is, those with a greater than average probability of loss. Applicants who are motivated to purchase coverage because they are aware of a medical problem that is not yet evident to the underwriter can select against the insurer. This is of concern to both group and individual insurance markets, but particularly to the latter. Group insurers try to protect themselves against adverse selection by using certain group underwriting techniques. For example, groups organized for the purpose of obtaining insurance are likely to include a disproportionate number of higher risks. Therefore, group insurers usually write coverage only for groups that exist for reasons other than for the purposes of obtaining insurance.

Employment-based groups are especially attractive to insurers. There generally is a flow of members into and out of such groups so that the average age and therefore the average risks of these groups do not increase much over time. Employees also typically comprise a generally healthy group because of the implicit (and sometimes explicit) health standards required by employers for hiring and retaining workers. Employees whose health is good enough to meet employment standards are generally better than average risks for insurance purposes. The families of employees, on the other hand, generally represent average risks.

The distribution of insurance costs in group versus individual insurance is also a critical difference, because it bears on the overall affordability of each type of health insurance product. In most cases, group members do not pay the full costs of their health insurance protection. Instead, the sponsor of the group plan—for example, the employer—usually contributes the major portion (sometimes all) of the premium costs. Without these contributions, premiums charged each member in the group would be likely to vary with the known risk, so that they would increase with age and could eventually become quite large for the older members. Charging the actual average group rate without an employer contribution could also lead to little or no enrollment among younger members of the group who might obtain lower-cost insurance individually. Thus, the employer's contribution makes it feasible to charge all workers affordable rates that do not increase with age and do not result in asking younger persons to pay more. This type of cross-subsidy among group members is not found in much of the individual insurance market and is a major advantage of group insurance.

Adverse selection is a particular problem in the individual insurance market. Most applicants for individual insurance are seeking coverage for the costs of unknown or unpredictable losses. Some applicants, however, are motivated to obtain insurance, because they know that they may have a higher than average probability or even a certainty that they will require treatment.

### Relative Costs of Group v. Individual Insurance

Yet another very important difference between group and individual insurance is the non-benefit costs and the economies of scale in providing each type of insurance. Group insurance is essentially low-cost, mass protection. Group insurance is also written without assessing each individual, thereby removing a source of considerable underwriting expense.

The administrative costs of marketing, acquiring, and maintaining individual accounts—as a percentage of premium—are far greater than are ordinarily incurred in the group market. Thus, the amount of premium dollars available to pay benefits is much less for individual than for group insurance.

### Tax-Favored Treatment of Group Benefits

Finally, the tax treatment of employer contributions toward group insurance favors enrollees in group health plans in contrast to purchasers of individual coverage. Employer contributions to a group plan are deductible to the employer as business expenses and, more importantly, not counted as taxable income to the members of the group plan. Thus, group insurance provides a greater after-tax value to group members than comparable wage or salary payments. Put differently, the cost of individual insurance is greater than the comparable cost of the same coverage in a group, because all of the costs of individual coverage is paid with after-tax dollars, while some or all of group coverage costs are financed with pre-tax dollars. (The Tax Reform Act of 1986 provides a limited tax subsidy toward the purchase of individual insurance for some self-employed persons) (1161 of the Tax Act of 1986).

### Underwriting Groups

In the private insurance marketplace, the characteristics of an acceptable group are determined by each insurer, subject to State restrictions relating to group insurance. Different insurers have different business goals and market segments in which they are particularly interested. Their underwriting rules are designed with these goals in mind. Group underwriters will select group risks whose expected claims experience will meet the standards established by each insurer for a plan of benefits and will set a rate to cover those expected costs.

As noted above, most group insurance is not medically underwritten. Instead, group underwriting involves examination of the experience of a group as a whole in terms of the following risk classification factors: size of the group, industry, composition of the group, location, plan of insurance, cost-sharing, administrative arrangements, and previous claims experience of the group. Larger groups are generally experience-rated, meaning that the premiums charged are based on the actual amount of claims payments made on behalf of the group in a prior period, usually the preceding year.

The capacity to spread risks in a group diminishes as the group becomes smaller. Most insurers, therefore, employ special rules for underwriting smaller groups. Because of the limited spread of risk, the experience of small groups is generally pooled with other small groups, and all groups in a particular category are treated as a single risk for rating purposes. Because the potential for adverse selection is quite high in small groups, many insurers apply especially restrictive underwriting standards—including the imposition of preexisting condition limitations, plan or benefit restrictions, etc.—that are not applied to the larger groups.

Very small groups (2 to 15 lives) are often medically underwritten in much the same manner as applicants for individual coverage (see below). In such cases, the insurer requires proof of insurability from each member of the group (including their potentially covered dependents). Where a member of the small group is determined to be uninsurable, the insurer may respond in a number of different ways, but generally the entire group is declined. In group plans where the individual pays a portion of the premium, people who elect not to enroll when first permitted to do so may also be medically underwritten if they seek coverage later on, in order to prevent adverse selection against the insurer. These individuals are commonly referred to as "late applicants."

### Underwriting Individuals

As premium rates are based on expectations, and not on certainties, the underwriting of individuals involves placing individuals in classes with about the same expectations of loss. "Preferred risks"—that is, those with average or less than average expected losses—will be accepted for insurance. Those with higher than average expected losses may be accepted but under special conditions. Those with the highest expectation of loss are declined and deemed uninsurable, except in some States where Blue Cross/Blue Shield (BC/BS) is required to accept all applicants (i.e., "open enrollment" is required).

### Underwriting Factors

The largest portion of the health insurance premium consists of expected claims (or benefit) costs. This amount is determined by the morbidity of the insured policyholders. Morbidity refers to the estimated frequency and severity (or average magnitude of loss) of illnesses and accidents in a well-defined class of persons. The probability of loss and the average severity are affected by such risk selection or classification factors as:

age, sex, health status and history, amount of benefits, financial status, occupation, and certain other factors. Each insurer prescribes its own range of acceptable risk-selection factors.

Insofar as health insurance is concerned, the two most important risk factors affecting individuals are age and current and future health status. For almost every type of benefit, both frequency of use and severity of illness increase with age. Underwriting guidelines developed by insurers often require more frequent use of medical examinations and requests for attending physician statements from older applicants for individual insurance coverage. Claims costs for different benefits often vary by gender, so sex is also a factor.

The goal of the underwriter is to determine whether insurance can be issued at "standard" rates, offered at "substandard" rates or with other limitations, or whether insurance should be refused (declined) altogether. The current and future health of an applicant is obviously important. When the applicant is already ill, disabled, or undergoing treatment at the time of application, coverage will not ordinarily be extended at all or if approved, will not cover the illness. If the impairment is minor, a policy might be issued with a preexisting condition limitation or waiting period in the contract. But if the condition is more serious, the application may be postponed or declined altogether. Thus, through an assessment of present medical condition and past medical history, the probable effect of future health status on expected claims experience is evaluated. For example, most health insurers deny any applicant whose probability of disease exceeds three times the average for his or her sex and age (HIAA manual). Under these standards, human immunodeficiency virus (HIV) infection far exceeds the limit of insurability for both life and health insurance. Insurers estimate that the mortality for an asymptomatic 35-year-old man infected with the HIV virus is 44 times, or 4,400 percent, that expected of a healthy, non-HIV-infected 35-year-old (81).

Applicants for individual coverage are assessed from three perspectives. First is the health history of the individual applicant. A history of past illness or accident will be given weight depending on: the severity of the original ailment, degree of permanent impairment (if any), possibilities of recurrence, complications that may develop, etc. Certain types of impairment have high recurrence rates (e.g., peptic ulcers), while others may have little or no bearing on future risk for claims (e.g., bone fractures, appendicitis), especially if a reasonable time has elapsed without complications. Conditions that are chronic and that also produce severe losses (i.e., involve high costs and large claims) may result in declination altogether. Second, certain family health information may be requested relating to the health of parents, children, and spouses. Generally, such information is more important to life insurance than to health insurance underwriting, but it may have some bearing on the applicant's future health as well (e.g., family history of diabetes).

Finally, the applicant's current physical condition is evaluated. Depending on this assessment (including judgments by the applicant himself and the insurance agent's observations about the applicant), certain tests or studies may be requested (e.g., blood chemistry, urinalysis, electrocardiogram), depending on the age or kinds of coverage sought.

Some States have legislated certain limitations on the underwriting process, precluding insurers from rejecting or separately rating certain persons (141). Typically, such provisions preclude refusal to issue coverage solely because of a physical handicap or some other circumstance pertaining to the applicant's health status. These restrictions on insurer underwriting are discussed elsewhere in this chapter.

## INDIVIDUAL INSURANCE MARKET

The individual insurance marketplace, compared with group insurance, is very small and consists of several different segments. The first of these is the "primary permanent" market, consisting of persons who generally look to individual insurance for their principal health benefit protection and who have the means to purchase such coverage. This market is not as significant as it once was, because many of the writers of group benefits—such as Blue Cross and Blue Shield plans—have expanded their group market offerings down to and including very small groups (e.g., two to nine members).

A second, but increasingly important part of the individual marketplace is the "supplemental" individual insurance area. This, too, is something of a special market that serves the narrower insurance needs of people whose basic health benefit requirements are already satisfied through some kind of group coverage arrangement or through Medicare. The consumers in this market are looking only to supplement the benefit design features of that group insurance. "Medigap" insurance for the elderly is an example of this type of protection. Cancer insurance is another example. Cash-benefit type plans are frequently marketed as supplements to other forms of benefits.

A third segment of the individual market is sometimes called the "primary interim" market. This consists of individuals or families caught between group coverage options, usually because of a break in the insured's connection to a sponsor of group benefits (e.g., through job loss, caused by prolonged illness and/or disability, voluntary separation from work, death of the worker, etc.). These persons usually seek individual insurance coverage on an interim basis. It is in this latter market that problems relating to the availability and/or affordability of private insurance options for certain individuals are often found.

Many of those interested in individual insurance—sometimes on a permanent, sometimes on a temporary basis—are those who have converted from a group policy.[3] Once a converted policy is issued, the administration of the policy follows that of other forms of individual insurance, including premiums paid directly by the insured to the insurer. Those who take the opportunity to convert often do so with the expectation of medical expenses and are generally poorer than average risks.

Companies that wish to compete in the individual health insurance field must price their products low enough to be competitive with other offerings and affordable to potential buyers but also high enough to cover expected claims and administrative expenses, and provide a return on capital. Understanding this objective helps to explain the importance of the underwriting function, or risk classification process, in the individual health insurance field. If, after deciding on the kinds of business it wishes to have, an insurer prices its products on the basis of assumptions that later prove erroneous—including estimates about expected future claims—the company will lose money. If the assumptions about expected claims are very wrong, and the resulting losses severe, the company may even face solvency problems that could impair its ability to meet other contractual obligations. The selection and rating processes are used by the companies that medically underwrite coverage in the individual marketplace to minimize such risks for the insuring organization. Unless private companies are allowed to exercise reasonable control over risk selection, they face possible failure as insuring organizations. This is because a considerable number of persons would wait to obtain insurance until shortly before they expect to incur large health costs and would drop coverage when their health care needs were no longer significant.

The individual insurance market is not regarded by many insurers as an efficient, effective, or profitable insurance line, and over the years the number of major insurance companies involved in the individual insurance field has diminished. Individual insurance products are viewed by many as inefficient because of the high expense ratios needed to support the costs of acquiring business, the expensive underwriting processes required, and the costlier distribution system. These factors reduce significantly the amount of premiums that can be returned in the form of benefits.

Profitability for individual insurance products is largely a function of actual claims experience, expenses, and persistency (i.e., the degree to which policies are renewed by the insured through continued payment of premiums), relative to the assumptions used in pricing. Investment income, which is a major factor in the group market, is not ordinarily a major contributor to earnings on individual insurance. The ability to earn a profit, therefore, is very sensitive to pricing assumptions, such as inflation projections and the willingness of regulators to view rate increases as reasonable.

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[3] Conversions represent a not insignificant portion of individual enrollments in some Blue Cross/Blue Shield plans.

The capacity of insurers to adequately price any insurance product depends on their ability to estimate risks. To assess the risks presented by an individual applicant for insurance, the insurer must gather as much information about the applicant as it deems needed to assign the individual to an appropriate class of risk. Insurers argue that they must have reasonable access to knowledge that has a significant bearing on the risk assignment process (148).

In order for rate equity to be fair among classes of insureds, premiums must also be reasonably related to the degree of risk involved for the class. Under this theory, two policyholders buying individual insurance and presenting approximately the same risk in terms of expected claims and expenses are expected to pay the same premiums. If their risks differ, the premiums should differ as well. Unless insurers have access to and can use pertinent information in the risk categorization process, high-risk individuals can become insured without paying premiums commensurate with their risks. Failure to use underwriting tools to identify different risks will result in the subsidization of high-risk persons by low-risk groups. If this subsidization is inadvertent or undisclosed, it is unfair to the low-risk groups. Even if disclosed, it will induce those benefited to accept insurance and those overcharged to reject it, regardless of the inherent efficiency of the insuring mechanism.

Both the marketplace and regulatory policies impose limitations on the charges assessed to low-risk groups to support high-risk individuals. Premiums that are high because of the expected experience of higher-risk individuals that are covered will result in lower-risk individuals seeking insurance elsewhere from competitors who underwrite differently, or they may drop insurance because the benefits of insurance are not worth the cost to them. Regulators, too, must be concerned that premiums are not only reasonable from the consumer's point of view, but also that they are adequate to assure the solvency of the insurer. Thus, competitive pressures of the marketplace introduce real limits on the ability of insurers to accept heterogeneous risks in a single pool.

## Predictive Testing—Underwriting v. Discrimination

Until recently, the need of insurers to inquire about and/or use tests in the underwriting process for individual coverage was generally accepted by many in the insurance industry and by the regulatory community. Past regulatory concerns have focused not so much on the use of test information for underwriting purposes, but rather on the need to preserve test result confidentiality. High-risk individuals are especially concerned about privacy issues and about potential discrimination in employment, housing, or other areas, if their health circumstances are known. As a result, many State insurance departments developed specific policies regarding insurance company use and disclosure of medical information about applicants and insureds, including test results. The National Association of Insurance Commissioners (NAIC) has developed a Model Information and Privacy Protection Act that has been adopted by a number of States to deal with disclosure of personal or privileged information, including unauthorized disclosures of information to employers (123). Other States, though not using the NAIC model law, have comparable requirements of one sort or another (see app. C).

In recent years, however, many of the States have gone beyond confidentiality concerns to prohibit certain kinds of underwriting approaches that have been deemed by State legislatures as discriminatory. For example, in 1987 Maine and North Carolina approved laws prohibiting discrimination in issuing, continuing, or cancelling insurance policies, or charging higher premiums solely because of certain physical handicaps (141). Maine prohibits discrimination against those who are blind, partially blind, or have physical or mental handicaps unless discrimination can be justified by sound actuarial practice. North Carolina prohibits discrimination solely on the basis of blindness, partial blindness, or partial deafness.

Denial of coverage may not be based on the handicap alone.

Other laws have been approved in recent years in some States prohibiting rating or rejecting persons exposed to a drug (DES) linked to cancer in the offspring of certain women or persons having certain genetic characteristics, such as sickle-cell traits. At least eight States have adopted NAIC guidelines barring insurers from using sexual orientation in the underwriting process or in the determination of insurability, premium, terms of coverage, or nonrenewal (212, 213).[4]

The specific rulings from many insurance departments about underwriting limitations seem to have two major goals: first, to assure that insurer practices adequately safeguard against discrimination and breaches of confidentiality, and, second, to assure that underwriting decisions are related to the nature and degree of risk covered or expenses involved. As in the case of Maine, Wisconsin demands that the factors that are used for underwriting purposes are justified. But Wisconsin has also concluded, for instance, that an applicant's sexual orientation cannot be used as a factor in the underwriting process (274).

## Predictive Testing and AIDS

The AIDS epidemic has brought about a great deal of attention to the problems of the high-risk uninsured and the appropriateness of predictive testing in the underwriting process, particularly in individual health and life insurance markets. In an effort to assess the levels of risk presented by individual applicants, some insurers ask questions directed specifically at the AIDS risk. Others seek to have applicants physically examined, including blood testing for AIDS antibodies. Still others are looking for indications of a recent history of sexually transmitted diseases (STD). (See box 2-A for a description of how one insurer handles applicants who may be AIDS antibody positive.)

These steps have provoked considerable concern among those who are in the highest risk categories for potentially contracting AIDS, AIDS-related complex (ARC) or other AIDS-related disorders. Consumer and advocacy groups are particularly worried about confidentiality issues and discrimination—particularly in the workplace—and about the ability of some persons to obtain health or life insurance coverage in the individual marketplace. AIDS advocacy groups have also charged that much of the antibody testing now being done is not appropriate or reliable testing for underwriting purposes. The tests, it is asserted, may indicate the presence of the AIDS virus, but not the disease itself.

Regulators and legislators throughout the country have been urged to pass laws or adopt regulations that limit or ban the use of AIDS antibody testing or test results as a basis for making underwriting decisions. The NAIC has been very active in the formulation of policies relating to insurer medical/lifestyle questions and underwriting guidelines affecting AIDS and ARC (212). Among State legislation on AIDS, California has passed a law prohibiting the use of the AIDS antibody tests or their results—but not other tests reflecting immune function—for the determination of insurability. Florida, Maine, and other States do not prohibit the use of AIDS antibody tests, but disallow questions regarding prior antibody testing history. The New York Department of Insurance held that the antibody tests are not diagnostic, because they only indicate exposure to the AIDS virus, not the presence of the disease. It attempted to prohibit AIDS antibody testing in underwriting and rating health insurance or in the denial of claims, but was denied by the State Supreme Court in April 1988.

The District of Columbia has adopted the most restrictive legislation regarding AIDS testing and insurance. The legislation prohibits the use of all AIDS-related tests for a 5-year period, including tests for AIDS antibodies, tests for the condition of the immune system, and tests to identify the existence of the AIDS virus itself. The legislation further prohibits the use of personal characteristics such as age, marital status, geographic area of residence, occupation, sex, or sexual orientation for the purpose of seeking to predict whether any individual may in the future develop AIDS or ARC.

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[4] Including Colorado, Delaware, Florida, Iowa, Oregon, South Dakota, Texas, and Wisconsin.

**Box 2-A.—How One Insurer Handles Suspected Seropositives: Metropolitan Life's Policy**

This information is taken from "Impact on AIDS on the Health Insurance Industry," a speech by Philip Briggs, vice-chairman, Metropolitan Life Insurance Co., September 30, 1987, to the Institute for International Research Conference on AIDS.

Insurance testing for AIDS primarily concerns three groups of people:

- Those applying for individual life or health insurance.
- Those in small group insurance plans (usually from 2 to 49 people).
- Those who originally do not accept large group coverage but later apply for the insurance.

Metropolitan Life requires the HIV antibody test when an applicant seeks a substantial amount of coverage, and when the applicant has symptoms possibly suggestive of AIDS. We use two ELISAs and a Western blot. Where such tests are prohibited, we use T-cell testing. No testing is performed without the applicant's consent. If the person declines the test, the application is marked "no action" and filed.

An application turned down because of a seropositive test is sent to the medical director, where the information is distributed strictly on a need-to-know basis.

To determine if applicants want to know about their seropositive test, we first tell them there was a significant result from their blood test. Then if they return a signed authorization, we offer the information to them or their doctors.

In group insurance, premiums and rates can be changed annually. But this may not be practical or desirable. Instead, insurers might suggest redesigning the health plan to included some of these features:

- Longer probation periods.
- Limitations on benefits that involve many conditions in addition to AIDS.
- Add limited coverage clauses to plans that do not have them.

SOURCE: "How One Insurer Handles Suspected Seropositives Metropolitan Life's Policy" *AIDS Patient Care*, 2(1):6 February 1988.

Wisconsin's experience in developing AIDS-related policies brings a different focus to some of the specific issues relating to predictive testing and insurance underwriting. In the fall of 1985, the Wisconsin legislature amended a law passed earlier in the year prohibiting insurance companies from requiring individuals to take the AIDS antibody test or to reveal the results of tests already taken. The provision also prohibited insurers from basing rates or any other terms of coverage on whether an applicant had taken the test or had revealed the results of a test already taken. The amended law, however, allows insurers to use a series of AIDS antibody tests which the State epidemiologist finds to be medically significant and sufficiently reliable for detecting the antibody and which the Commissioner finds and designates by rule to be sufficiently reliable for use in underwriting of individual life, health, and accident insurance.

The State epidemiologist did determine that a series of multiple ELISA (Enzyme-Linked Immunosorbent Assay) tests coupled with a Western blot test is medically significant and sufficiently reliable.

The Commissioner's office found, however, that these rulings leave unanswered the much broader—and much more significant—public policy question of how the costs of treating the AIDS pandemic should be dealt with, and particularly for those who are denied coverage sought on an individual basis.

## REGULATION OF HEALTH INSURANCE

There are two broad categories of health insuring organizations in the marketplace—commercial insurance companies and hospital service (Blue Cross) and/or medical service (Blue Shield) plans.

More than 800 insurance companies and 77 BC/BS plans write group and individual health insurance contracts in the United States. In addition to the insurers, there are also hundreds of health delivery organizations, such as health maintenance organizations (HMOs) and competitive medical plans (CMPs) that, in addition to performing a financing role, actually arrange for the provision of health services for persons enrolled in their plans.[5]

## Regulation of Insuring Entities

All of the States have established insurance laws that require insurance companies to meet a variety of financial and other requirements in order to obtain a license to do business in the State. The exact requirements vary widely from State to State but ordinarily stipulate certain amounts of financial resources needed to establish solvency as an insurer (289). The specific financial requirements vary according to such factors as the kind of insurer involved (e.g., a stock versus a mutual company), how the firm is to be organized (e.g., as a domestic versus out-of-State company), the number and/or combination of insurance lines (e.g., life, casualty, accident and health, etc.) a company proposes to market, and the insurance experience of a firm prior to the licensing request. Many States also require companies to maintain membership in a guarantee association as a condition of doing business to cover the liabilities of impaired or insolvent companies.

Hospital service (Blue Cross) and medical service (Blue Shield) plans are ordinarily exempted from State commercial insurance law but are granted franchises to do business and are regulated under separate enabling legislation (289). BC/BS plans usually do not have to meet the initial capitalization requirements required of commercial insurance companies, but in many other respects the plans are treated like commercial insurers in such matters as policy filing and approval, reporting and examination requirements, and investment limitations. On the other hand, BC/BS plans are frequently subject to a rate-making process that does not generally apply to commercial insurers. Involved in this process are review and approval of subscriber premiums, public rate hearings, benefit modification approvals, and the review and approval of payment agreements and fee schedules with providers of health services. In response to growing competitive pressures, an increasing number of plans are seeking legislative approval to reorganize themselves as mutual insurance companies instead of traditional hospital or medical service corporations under State law.

## Regulation of Insurance Contracts

Generally speaking, the statutory requirements regarding group contracts differ from those applicable to individual contracts. In essence, regulation in the individual contract area is somewhat more rigorous and also more standardized than is found in the group contracts area. This is due in large part to the view that people who are individually insured lack expertise about many insurance matters and are not in a position to negotiate the terms of contracts with the companies that specialize in this field. Group insurance arrangements, on the other hand, involve negotiations between more equally situated parties who can better protect their own interests in entering into a health benefits contract. Thus, group insurance laws are usually not as detailed or as prescriptive as the statutes affecting individual contracts, especially with respect to policy language, though some States do require certain uniform provisions in the group area. Some States require the filing of group rates and information justifying rates; others require rate information only when requested by the regulatory authority. However, the States generally do not regulate group health insurance rates on the theory that health insurance written on a group basis has a history of being quite competitive.

All States require that individual health insurance policy forms be filed with the appropriate regulatory authority before being used. Most States also require similar filings of group insurance contracts. Insurance laws generally authorize an insurance commissioner (or comparable authority) to disapprove policies if they contain unjust, unfair, inequitable, misleading, or deceptive provisions. Many States also permit their commissioners to disapprove contracts on the grounds that the benefits provided are unreasonable in relation to the premium charged for protection; that is, the premiums must not be excessive. Actuarial tests have been developed for making these assessments. Many of the BC/BS plans are required to obtain prior approval of individual subscriber rate schedules.

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[5] The regulatory framework governing alternative delivery organizations is not reviewed in this report.

Some States require the advance approval of individual policies, riders, endorsements, and other related contractual materials (e.g., the application form). Most States, however, make use of "deemer" provisions which provide that policy forms and related items will be "deemed" approved, unless the insurance authority advises to the contrary within a specified period of time. Some States permit the immediate use of new or revised policy forms without any "deeming" period until some disapproval action, if any, is taken. States may also require an insurer to obtain prior policy approval from the State in which the insurer is domiciled before it may be offered in their own jurisdictions.

States frequently apply statutory provisions that prohibit certain types of discriminatory practices in issuing, continuing, or cancelling insurance policies, or prohibit charging higher premiums solely because of certain physical handicaps such as blindness, mental handicaps, etc., unless the discrimination can be justified by sound actuarial practice (123). Other anti-discrimination statutes require that underwriting decisions be related to the nature and degree of the risk covered or expenses involved. Thus, certain factors—some of which are discussed elsewhere in this report—may be barred from use in making underwriting decisions for individual coverages.

The policy form and supporting material filed by an insurer are assigned within an insurance department to an insurance examiner, who determines that the documents are in compliance with various statutory and administrative standards established by the State for policy form and content. A typical filing would include several copies of the actual policy form, the application for insurance, information regarding rates and the classification of risks used in connection with the policy, an outline of the rules pertaining to any limits imposed with respect to eligible risks, and statements setting forth anticipated loss ratios (ratios of expected claim payments to premiums).

Many States also have laws governing some aspects of group insurance contracts, such as who constitutes a group for group benefit purposes. In addition, many States have adopted laws requiring group contracts to contain certain types of mandatory conversion and/or continuation-of-coverage provisions.[6] A conversion privilege permits members of a group and their dependents to continue their insurance protection on an individual basis when their coverage under a group plan ceases, without proof of insurability (i.e., without regard to information that would affect the individual's acceptability for coverage under an individual contract). Such requirements are often required not only for workers who leave the employer sponsoring the group plan, but also for certain spouses and dependents in the case of the insured's death or dissolution of marriage. The continuation is an extension of the original group plan at the same premium, though the separated group member (or his or her spouse or dependents) pays the full premium costs of coverage, including any employer contributions made on behalf of members still in the group.

## Mandated Benefit Laws

In addition to requiring compliance with certain contract provisions, many States have adopted various mandated benefit laws (123). Some of these statutes require that contracts include certain specified benefits. Existing contracts are usually amended to include required coverages on their renewal dates. Alcoholism, drug addiction, maternity coverage, etc., are among the areas frequently addressed by mandated benefit laws.

Rather than mandate specific coverages, some States require insurers to offer prospective buyers certain benefits, but the inclusion of those benefits in the group contract is not required. Other State statutes mandate payment to certain providers by precluding insurers from distinguishing among the providers of certain health services (for payment purposes) as long as those providers are licensed or certified by the State and are operating within the scope of their licenses or certifications.

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[6] The Federal Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Public Law 99-272) has a similar provision regarding continuation of coverage.

## Premium Taxation

States (and a few other jurisdictions) impose taxes on premiums received by insurance companies, including premiums for health insurance. In general, these taxes vary from State to State, by the type of company involved, and whether the insurer is an out-of-state or domestic company. The tax rates also vary, but most are in the 2 to 2.25 percent range. Most States do not impose premium taxes on Blue Cross or Blue Shield plans, though several States do impose some charges on them in lieu of premium taxes.

## Regulatory Authorities

In each of the States and the District of Columbia, some authority is designated to regulate insurance, including health insurance. (Health insurance is only one of the concerns of these authorities.) In some cases, this is an independent State agency, such as a department of insurance; in others, the authority is a constituent of some other entity with broader responsibilities than insurance alone, such as business regulation. The insurance departments, however called, are headed by an official (usually appointed, but in some instances, elected) known as a commissioner, superintendent, or director of insurance (in a few States, the attorney general's office performs certain regulatory functions, usually relating to BC/BS plans). Insurance authorities are charged with enforcing the insurance, hospital, and medical service corporation and other State laws pertaining to insurance.

Enforcement is carried out through the issuance of regulations, rulings, and other formal processes, but also frequently through letter communications and informal discussions and meetings. Not all regulatory policy, therefore, is clearly spelled out in official, secondary source documents, or materials published by State insurance regulatory authorities.

The powers of commissioners and their staffs to affect the business of insurance are numerous and include the power to issue or withhold licenses; examine an insurer's records and financial condition; approve insurance products; surveillance and, in some cases, prior approval of rates; and the conduct of audits of operations. Other regulatory supervision focuses on the licensing of agents, advertising practices, disclosure requirements, and policyholder complaints.

## Federal Laws Affecting Health Insurance

The McCarran-Ferguson Act (Public Law 15, 79th Congress) provides that the States have major regulatory responsibilities with regard to the business of insurance. In addition, several Federal laws affect health benefit plans, particularly group plans. For example, the Federal tax code has an important impact on health insurance, such as the exclusion of employer contributions for health benefits from the taxable income of workers. Legislation such as ERISA (the Employee Retirement Income Security Act), the HMO (Health Maintenance Organization) Act, and Medicare each affect the design of many private health benefit programs. COBRA (Consolidated Omnibus Budget Reconciliation Act of 1985) (Public Law 99-272) mandates that employers provide continuation of coverage for those employees and their dependents who would otherwise lose eligibility because of reduced work hours or termination of employment. Congress has also enacted laws prohibiting certain discriminatory practices relating to age and sex in the provision of health benefits for workers and their dependents.

# THE HEALTH BENEFITS MARKETPLACE

## Development of Health Insurance

The private health benefits marketplace is a complex and competitive arena that involves many different parties concerned with the design, sale and distribution, cost, regulation, and performance of the health benefits industry.

The health benefits market is dominated by concerns with group benefits, since most nonelderly Americans are protected against the costs of medical care through group benefit plans usually sponsored by their employers. Modern group health insurance evolved during the Depression with the development of hospital service plans (Blue Cross) that paid for specified hospital room and board and ancillary services for a pre-determined monthly payment or premium. Also during the 1930s, commercial insurance companies, that did provide some sickness and accident coverages on an individual basis, began to offer cash (or indemnity) benefits toward the costs of health care as part of group contracts.

During the Second World War, interest in group health benefits began to expand as a component of many collective bargaining activities, because such benefits were not subject to wartime wage and price control limitations. Even greater interest in employer-sponsored group health benefits emerged soon after the War, when the Supreme Court ruled that such benefits were a legitimate part of the labor-management bargaining process.

Initial worker interest in group health benefits focused on hospital care, where new technological advances in surgery and anesthesia were taking place and where the largest and most difficult-to-budget-for expenses were incurred. Expanding use of surgical procedures led to a broadening of basic hospital benefits to include physician surgical expenses as well. During the 1950s, group health protection grew rapidly to cover non-surgical services provided by physicians in hospitals, and then to other medical care provided in office and other non-hospital settings. Today, many workers enjoy comprehensive group benefit protection that often encompasses a wide range of medical care, including dental, vision, and other non-medical benefits as well.

## The Insured Group Market

Until the 1970s, most group buyers of health benefits—such as employers—purchased coverage from a commercial insurance company or BC/BS plan. Unless the purchasers (e.g., employers) were very large, however, they generally did not have much influence over the design, financing, or administration of the health plan. In the smaller group marketplace, the insurers themselves developed and marketed a range of standardized products from which an employer could choose, allowing for some modifications to meet the employer's specific needs.

In exchange for premium payments, the group buyers transferred to the insuring entities—insurance companies or BC/BS plans—the financial risks of paying benefits. It is the transfer of financial risk that is the essence of the insured health benefits plan. In most instances, the insurers also performed other functions relating to the contract, such as help in the design of benefits, collection of premiums, payment of claims, and other administrative functions. Thus, the group buyer purchased a "package" of insurance services. Larger group health purchasers (e.g., multistate employers or large associations) often have their own in-house staffs of benefits specialists, including experts in group benefits contracting. These employers, using their market power as buyers, will generally invite proposals from competing insurers to provide health benefits for their workforce on the basis of specifications developed by the employer's own benefits staff, by insurance brokers, or by health benefits consultants working for the buyer. As a result, larger group plans are generally tailored to meet the needs of the purchaser and are offered on a bid basis. Thus, knowledgeable buyers and sophisticated suppliers make the group health benefits marketplace highly competitive.

The commercial insurance companies and the BC/BS plans—which are basically health care financing and marketing arrangements—are not the only sources of group benefit coverage. Significant growth has also occurred in the numbers of health delivery organizations (such as health maintenance organizations and competitive medical plans) that provide, as well as finance, benefits. This growth has further intensified competition in the marketplace.

## Self-Insurance

The most important competitive development in the group health benefits market during the last 15 years has been the "unbundling" of the traditional health insurance product.[7] Major changes have occurred in the development of new and alternate methods to finance and/or administer health benefit programs. The principal source of this competition for traditional insurers in recent years has come from their own potential policyholders—the employers—who have elected to self-insure their benefit plans and purchase related administrative services separately.

During the economic ups and downs of the early 1970s and early 1980s, many larger corporations with health plans experienced significant pressures on profits and cash flow. At the same time, health care inflation and rising utilization resulted in sharp increases in the costs of their group health plans. As these costs increased, employers began to consider alternative ways to control expenses, including alternate methods for financing benefits and for administering claims.

Many group buyers, particularly those with more stable workforces, noted that they experienced relatively little fluctuation in their volume of health claims, and that the annual increases in their experience-rated premiums were reasonably predictable by applying a standard medical care inflation factor. This straightforward relationship brought home the fact that the insurers were relieving the employers of very little risk, except perhaps to protect one year's cash flow. In effect, the employee groups covered by large corporations had grown to such a size as to render of little value the essential function of insurance—i.e., reducing the risk by pooling independent exposures. In fact, if the group is composed of better than average risks, it can reduce its benefit costs by not having to share in any of the costs of other risks taken on by an insurer.

The logical next steps were to redesign the financing mechanisms altogether. Many insurers responded to new demands from their policyholders by entering into a variety of arrangements through which the employers or groups retained or "self-insured" part or all of the financial risks for the payment of claims. Today, self-insured health benefit plans of various types and design are the predominant form of group coverage in the marketplace among larger employers and groups. In addition to their traditional insured group products, most major group health insurers (commercial and BC/BS) now offer various types of new products, including administrative services only (ASO) or claims services only (CSO) programs because of the demand from group sponsors for such arrangements.

Self-insured plans offer several key advantages to employers. First, self-insured employers are able to use and retain earnings on amounts that would otherwise be paid to and held by insurers to create claims reserves. Both commercial carriers and BC/BS plans are required, under various State laws, to hold reserves to cover claims that are due but as yet unpaid, in the course of settlement, or incurred but not yet reported. The actual amount of these reserves varies from case to case and from carrier to carrier, but they can represent a sizeable portion of the annual premium. The insurers earn interest on these reserve amounts. Competition, however, has led most insurers to negotiate a retention—that is, the amount retained by insurers for expenses, for contingencies, and for profits or for additions to surplus—with employers that reflects rate credits for the interest earned on the reserves. Many employers, however, felt that they could gain even more by holding onto these amounts in the first place.

Second, no State premium tax is applied to self-insured plans. A self-insured arrangement, therefore, depending on its design, can reduce or eliminate altogether the costs of State taxes on health insurance premiums.

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[7] The traditional insurance product consists of various components including risk assumption, financing arrangements, claims management, actuarial services, legal services, etc.

A third and very important benefit of self-insurance is that self-insured plans can avoid the requirements of State insurance law and regulation because of the Federal Employee Retirement Income Security Act, or ERISA. A provision in ERISA allows Federal law to preempt State laws, insofar as such laws relate to benefit plans covered by ERISA.[8] While an exemption from the general preemption rule for ERISA leaves untouched State laws that are designed to regulate the business of insurance, ERISA preempts laws that have a regulatory impact on employee benefit plans. Thus, self-insured plans need not comply with any of the State laws that require health insurance contracts to include specified benefits, comply with certain anti-discrimination standards applicable to insured plans, pay State insurance premium taxes, or participate in insurance pools for high-risk individuals. Much of the group benefits marketplace, therefore, is virtually unregulated by the States.

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[8] Section 514 of ERISA. Amendments to ERISA have provided for some State regulatory review of multiple employer trusts.

## THE OTA SURVEY[9]

### Introduction

Many insurance texts describe the principles of underwriting and the underwriting process.[10] Yet, there are few or no details on whom insurers test and what tests they require. A 1986 survey conducted by the Health Insurance Association of America (HIAA) and the American Council on Life Insurance (ACLI) gathered data on screening by insurers for infections with the human immunodeficiency virus (HIV) (127). This survey, however, had two important limitations. It did not provide a view of HIV testing in the context of other routine tests required by insurers, and it included neither Blue Cross and Blue Shield (BC/BS) plans nor health maintenance organizations (HMOs), a rapidly growing health insurance sector.

In an effort to fill this gap, the Office of Technology Assessment (OTA) conducted a survey of commercial carriers and BC/BS plans in July 1987, and a survey of HMOs in September 1987. Approximately 14.5 million non-Medicare individuals have health insurance without the benefits of group membership. Commercial carriers insure approximately 9.3 million (66); BC/BS, 4.2 million (203); and HMOs, approximately 1 million (146, 239). These are the principal individuals that must meet underwriting standards to obtain health coverage, and their insurers were the focus of the OTA survey.

The survey was developed in cooperation with HIAA, the national Blue Cross and Blue Shield Association (BCBSA), and the Group Health Association of America (GHAA). The purpose of the survey was twofold:

1. to collect basic information on individual underwriting practices and the use of medical screening by insurers, and
2. to document how health underwriters have responded to the AIDS epidemic.

The survey questionnaire varied little among the three target groups. Terminology was tailored to each, and some questions were modified to reflect differences in rating and enrollment practices. The survey of commercial companies is presented in app. D.

Overall, 84 percent of the total group of commercial carriers, BC/BS plans, and HMOs that were surveyed responded. Survey responses are summarized in table 2-1 and described below.

### Commercial Health Insurers

The commercial health insurance survey was targeted to those firms that sell individual policies. These firms are the principal health insurers who require some applicants to undergo diagnostic

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[9] This survey was published in February 1988 as the second staff paper in OTA's Series on AIDS-Related Issues. The staff paper is expanded here to include relevant data on group-based health insurance underwriting.

[10] Underwriting is the process by which an insurer determines whether or not and on what basis it will accept an application for insurance.

### Table 2-1.—Response to the Survey: Commercial Health Insurers, BC/BS Plans, and HMOs

| | Commercial insurers | BC/BS plans | HMOs |
|---|---|---|---|
| Total mailed questionnaires | 88 | 15 | 50 |
| Replied | 73 (83%) | 15 (100%) | 40 (80%) |
| fully responded | 62[a] (70%) | 15 (100%) | 16[b] (32%) |
| omitted (not relevant) | 9 (10%) | — | 23 (46%) |
| company liquidated | 1 | — | — |
| too late for inclusion | 1 | — | 1 ( 2%) |
| No Reply | 15 (17%) | — | 10 (20%) |

[a] One of the sixty-two responding companies had recently withdrawn from the individual health insurance market and responded only to those questions concerning small underwritten group policies.

[b] One of the sixteen responding HMOs does not allow individual enrollment but does accept small underwritten groups.

SOURCE: Office of Technology Assessment, 1988.

testing or physical examination.[11] The survey was sent to the 88 largest individual health insurers identified by the 1985 "Best's Life-Health Industry Marketing Results" (20). These 88 companies represented 70 percent of the commercial, individual health insurance market.[12] Two insurers not found on the Best list but reported elsewhere (217) to be "leaders" in individual health were included. Two companies reported on the Best's list were never located. Thus, the survey was sent to a total of 88 companies.

Eighty-three percent (73 of 88) of the commercial insurers responded, although one response arrived too late for inclusion and nine companies issued policies that were not relevant to the intent of the survey (table 2-1). These nine companies sold only cancer, intensive care unit (ICU), guarantee issue, or Medigap policies and were omitted.[13] Another company had been liquidated. Nevertheless, commercial participation was high; 62 companies (70 percent) completed the survey in time to be included in the analysis, representing approximately 57 percent of the commercial, individual health insurance market (20). (One company had recently withdrawn from the individual health market and responded only to those questions concerning group policies.) Response was especially strong among industry leaders. Of the 25 largest companies in 1985, 19 completed the survey (41 percent of the market), 4 were not relevant to the survey, and 2 did not reply.

Three health insurance populations were defined in the questionnaire:

1. **individuals**—those who seek insurance independently and without any association with an employer or membership group of any kind (also referred to as **direct pay** or **non-group** in the BC/BS survey and **self-pay** in the HMO survey);
2. **individually underwritten groups**—those groups that are too small to qualify for experience-rating and whose members must be individually underwritten (referred to in this report as **small groups**);
3. **other groups**—employee and other large groups that do not require individual underwriting (referred to in this report as **large groups**).

Survey respondents were asked to avoid including group conversions to individual coverage or Medigap policies in their responses.

It is important to emphasize that the surveyed companies were selected to target leaders in individual health rather than group-based insurance. Indeed, a significant number of the respondents do not sell group health insurance. Of the 62 survey respondents, 38 reported that they underwrite small group health insurance, and only 27 indicated that they offer large group coverage. While the survey's focus was on individual underwriting, these companies were asked to also respond to questions concerning their group underwriting practices.[14]

Companies were selected for inclusion in the survey regardless of HIAA affiliation. However, letters endorsing the survey were sent by HIAA, on OTA's behalf, to their 52 members. Companies providing confusing or incomplete data were called for clarifications.

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[11] Large group health insurers may test, but only in rare cases of so-called "late applicants." Late applicants are employees who are eligible for group health insurance but choose not to sign up until after the normal enrollment period. Employees who do not participate when first eligible may later choose to join when they know they soon will have a claim. Insurers often require proof of insurability to prevent such adverse selection (124).

[12] Market share calculations were based on 1985 direct premiums earned for collectively renewable, guaranteed renewable, and all other accident and health insurance.

[13] Cancer insurance provides coverage only for cancer. ICU policies cover only stays in hospital intensive care units. "Guarantee issue" refers to policies sold without regard to health status. Medigap policies are designed as supplements to Medicare coverage for the elderly.

[14] The response to group-related questions was sometimes poor, thus only significant findings are reviewed in this report.

The responding companies reported receiving a total of 2.24 million applications for individual health insurance each year.[15] The annual volume of applications ranged from 700 to 325,000. The largest insurers dramatically overshadowed the others. Although 70 percent of responding companies process no more than 33,000 applications annually, 6 firms alone accounted for 1.2 million applications, or more than half the annual volume of the entire group (table 2-2).

Twenty-eight of the respondents reported also receiving 436,000 small group applications annually. While most of these insurers (17 of 28) process fewer than 10,000, one company alone accounted for 100,000 small group applications or more than 20 percent of the annual volume of the entire group (table 2-2).[16]

## Blue Cross/Blue Shield Plans

There are 77 BC/BS plans nationwide, all offering some form of individual health coverage. BC/BS plans often operate under considerably different conditions from commercial carriers. Some plans hold open enrollment periods, all are regionally based, and many enjoy significant shares of their local health insurance market. These factors may play a pivotal role in underwriting policies.

Twenty-four plans (31 percent) in 15 States, 4 according to State mandate, accept anyone who applies for individual coverage, regardless of health status, during certain periods of the year. Seventeen (22 percent) of these "open enrollment" plans are termed "continuous," because they accept all applicants throughout the year (165). The implications for the underwriting process are significant. Because no individual standards of insurability are applied to open enrollment applicants, there is considerable adverse selection. In other words, people with poorer than average health expectations are more likely to apply for insurance than those with average or better health expectations. Most plans attempt to hold down premium rates for open enrollment subscribers by providing less comprehensive benefits relative to medically underwritten applicants. Others require open enrollment subscribers to pay higher premiums than underwritten applicants for identical coverage. Open enrollment coverage of high-risk applicants usually entails waiting periods before initial benefits may be paid and may impose limitations on coverage of preexisting conditions.

Even though open enrollment plans never deny an application, applicants may be required to furnish evidence of their health status, including an attending physician's statement (APS).[17] Individuals enrolling in an open enrollment program

**Table 2-2.—Commercial Health Insurers Annual Volume of Applications for Individual and Small Group Coverage**

| | Individual policies | | Small group policies | |
|---|---|---|---|---|
| Average number of applications per year | Number of companies (n=61) | Percent of companies | Number of companies (n=38) | Percent of companies |
| 100-15,000 | 26 | 43% | 19 | 50% |
| 15,001-30,000 | 16 | 26 | 5 | 13 |
| 30,001-45,000 | 5 | 8 | 1 | 3 |
| 45,001-100,000 | 5 | 8 | 3 | 8 |
| More than 100,000 | 5 | 8 | 0 | — |
| Not available | 4 | 7 | 10 | 26 |
| Total | 61 | 100% | 38 | 100% |

SOURCE: Office of Technology Assessment, 1988.

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[15] Four of the sixty-one individual insurers did not provide data on number of applications received annually.

[16] Ten of the thirty-eight responding companies (26 percent) that underwrite small group insurance did not report their application statistics.

[17] An attending physician statement is a report summarizing the applicant's recent health history that is prepared by the applicant's personal physician.

often have the option of undergoing medical underwriting, and even a physical exam, to determine whether they qualify for a more comprehensive benefit package at a preferable rate. In addition, health information may be required by the underwriter to develop benefit limits, exclusion riders, waiting periods for preexisting conditions, or premium rates.

Unlike commercial insurers, the BC/BS plans are regional and do not sell coverage outside a particular State, metropolitan area, or region. This has particular significance vis a vis AIDS, not only because of the disproportionate effect of the epidemic on certain locales, but also because of State and local regulations on screening for HIV infection.

The market share of many BC/BS plans, though decreasing in recent years, has historically overshadowed that of any individual commercial carrier. In some States, as much as half the population may be BC/BS subscribers. Such a secure market position can shape underwriting policies and allow a plan, for example, to enroll high-risk applicants.

Fifteen plans were selected for the OTA survey and were chosen to ensure representative geographic distribution, variations in market share, location in areas of low and high AIDS prevalence, and differing policies regarding open enrollment (table 2-3). The survey was sent to the plans, on OTA's behalf, by the national Blue Cross and Blue Shield Association along with a letter of endorsement. All 15 plans completed the questionnaire and reported that they offer individual and large group coverage. Fourteen also underwrite small groups. Plans providing confusing or incomplete data were called for clarifications.

The commercial questionnaire was adapted for the BC/BS plans to include appropriate terminology and address BC/BS open enrollment and underwriting practices.[18]

**Table 2-3.—Characteristics of the 15 Responding Blue Cross/Blue Shield Plans**

| Plan characteristic | Number of plans (n=15)[a] |
|---|---|
| In an area of high AIDS prevalence . . . . . | 5 |
| Significant market share[b] (more than 38% share) . . . . . . . . . . . . . . | 7 |
| In a competitive market (20-31% share) . . . . . . . . . . . . . . . . . . . . . | 8 |
| Offers continuous open enrollment[c] . . . . | 4 |

[a] Some plans appear in more than one category.

[b] Market share data come from P. Fanara and W. Greenberg, "The Impact of Competition and Regulation on Blue Cross Enrollment of Non-Group Individuals," *The Journal of Risk and Insurance*, pp. 188-189, June 1985.

[c] An additional plan holds open enrollment, but it is limited to certain months of the year.

SOURCE: Office of Technology Assessment, 1988.

## Health Maintenance Organizations

HMOs are health care organizations that provide comprehensive services to enrolled members for a fixed, prepaid amount that is independent of the number of services actually used. As of March 1987, there were 654 HMOs in the United States, with enrollment exceeding 27.7 million members, or more than 10 percent of the U.S. population. HMO growth has been phenomenal. From 1981 to 1986, average annual enrollment increased 20 percent, while the number of plans increased by 48 percent. Thirty-four new plans started in the first 3 months of 1987 alone (147).

By assuming not only the insurance risk but also the responsibility for providing their members' health care, HMOs operate under significantly different conditions from either BC/BS plans or commercial carriers. Another important distinction is that while commercial insurers and BC/BS plans are governed solely by State regulations, many HMOs voluntarily adhere to Federal qualification standards as well.[19]

More than half the nation's HMOs are federally qualified, and 80 percent of HMO enrollment is in federally qualified plans (147). Federal qualification shapes HMO insurance practices including rate-setting, risk classification, coverage, preexisting conditions, and waiting periods. It requires that if an HMO accepts non-Medicare individual members, they must be either accepted at a community rate or rejected altogether. Exclusion riders and rated premiums are prohibited. In addition, benefits for preexisting conditions must be available upon enrollment because waiting periods are not allowed.[20] Medical screening of individual applicants is permitted, however.

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[18] References to "individual coverage" were replaced by "non-group/direct pay" coverage to reflect BC/BS terminology. Plans were asked to verify whether they offered continuous or noncontinuous open enrollment. Question II.B. in the commercial insurers survey (see app. D), which concerns the importance of nonmedical underwriting factors, was split into three parts, focusing on the actual proportion of BC/BS applicants affected by medical as well as nonmedical underwriting factors.

[19] The Federal Health Maintenance Organization Act of 1973, as amended (42 U.S.C. Sec. 300e et seq.), created an HMO office within the Department of Health and Human Services to regulate HMOs through qualification and ongoing compliance requirements. In order to become federally qualified, HMOs must meet certain financial, underwriting, and rate-setting standards and provide specified medically necessary health services (116).

State HMO regulation varies. While some States give HMOs considerable latitude with respect to nongroup underwriting, others are more restrictive than the Federal HMO Act. Minnesota, for example, allows medical screening, exclusion riders and experience-rating (315). In contrast, Ohio forbids medical screening of nongroup applicants during a mandated 30-day open enrollment period each year (283).

Most industry experts believe that individual enrollment in HMOs is rare. The Group Health Association of America estimates that no more than 4 percent of non-Medicare HMO members enroll as individuals (239). Many of these "self-payers" are "conversions" (i.e., former group members who have converted to individual enrollment because of a change in employment or marital status). Both the Federal HMO Act Regulations (42 CFR 417.108(e)) and The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Public Law 99-272) mandate that HMOs allow group members to convert to individual enrollment without providing evidence of insurability.

No national database identifies the HMOs that accept self-paying individuals. Because OTA was not able to ascertain which HMOs accept individual enrollment, the survey questionnaire was sent to the 50 largest local and national HMOs to first inquire whether the organization enrolled individuals other than on a conversion basis and, if so, to request that the HMO participate in the survey.[21] [22] Endorsement letters from GHAA were enclosed with the survey. Plans providing confusing or incomplete data were called for clarifications.

Eighty percent of the HMOs (40 of 50) responded.[23] Sixteen (32 percent) reported that they met the survey requirements and completed the questionnaire in time to be included in the analysis; of these, 15 (30 percent) accept nongroup individuals (i.e., on a non-conversion basis), eight (16 percent) underwrite small group, and 16 (100 percent) and 4 (25 percent) enroll community-rated and experience-rated groups respectively. (Note that one of the sixteen responding HMOs does not allow individual enrollment but does underwrite small groups.) The fact that close to one-third of the 50 largest HMOs enrolled nonconversion individuals indicates that HMOs may be playing a greater role in the individual health insurance market than previously believed.

The 16 plans that completed the survey had a total of 9.2 million members and one-third of the nation's total HMO membership. Membership for these HMOs ranged from 110,000 to more than 4.9 million; several were national firms that included from 6 to 24 local plans. The 23 HMOs that responded to OTA's letter but accepted neither nonconversion individuals nor underwritten groups had a total of 6.5 million members (147). Other responding plan characteristics are summarized in table 2-4.

Although the responding HMOs represent a substantial share of the national HMO membership, these older, established, and very large organizations are not necessarily representative of younger plans and recent entrants into the mar-

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[20] However, if an HMO applicant knowingly misrepresents his or her state of health, the plan may have grounds to terminate membership.

[21] The surveyed plans were selected from "The Interstudy Edge" report of HMO membership as of Mar. 31, 1987. Note that many of the 50 largest HMOs are national firms that may include as many as 37 local plans.

[22] The HMO survey instrument differed from the commercial questionnaire in several ways. Plans were asked if the HMO (1) accepted self-paying individuals other than on a conversion basis; (2) was federally qualified or had a nonfederally qualified subsidiary; (3) offered continuous or noncontinuous open enrollment; and (4) had individually underwritten groups, community-rated groups, or experience-rated groups. In addition, some terminology was changed to reflect HMO practice.

[23] However, one HMO responded too late to be included in the analysis for this report.

**Table 2-4.—Characteristics of the 16 Responding HMOs[a]**

| HMO characteristic | Number of HMOs (n=16) | Percent of HMOs |
|---|---|---|
| Federally qualified (FQ) | 9 | 56% |
| FQ with non-FQ subsidiary | 3 | 19 |
| Model type: | | |
| Network | 7 | 44% |
| IPA[b] | 5 | 31 |
| Staff | 3 | 19 |
| Group | 1 | 6 |
| Membership types accepted: | | |
| Self-pay individuals | 15 | 94% |
| Individually underwritten groups | 8 | 50 |
| Community-rated groups | 16 | 100 |
| Experience-rated group | 4 | 25 |

[a] An additional 16 HMOs responded to the survey but were excluded because they accept neither individuals nor individually underwritten groups.
[b] Independent practice association.

SOURCE: Office of Technology Assessment, 1988.

ket. Small, young HMOs are less likely to enroll individuals, be federally qualified, or operate on a not-for-profit basis (147).

## Survey Results

### Medical and Other Factors in Risk Classification[24]

**Commercial Insurers.**—The outcome of underwriting is risk classification, the final evaluation of whether the proposed insured will be covered on a "standard" or "substandard" basis, or not at all. Insurers were asked to list those conditions or impairments that they exclude from coverage, "rate-up" (i.e., require a more costly premium), or consider uninsurable. In general, the companies take a very similar approach to classifying risk. However, there are differences; some medical conditions or impairments that make the applicant wholly uninsurable by one insurer may just be excluded from coverage or rated-up by another. For example, although some companies are unwilling to underwrite applicants with any history of diabetes, others decline only juvenile diabetics and insure but exclude diabetes for other diabetic applicants. In some cases, severity of the condition is key. For example, if hypertension is controlled and moderate, a rated premium (i.e., more expensive) may be offered; if the hypertension is uncontrolled or severe, the applicant may be denied coverage altogether (table 2-5).

Most applicants for individual health coverage are classified as standard and can purchase insurance protection without extra premiums or special limitations. Three-quarters of the responding insurers (46 of 61) provided standard coverage to at least 60 percent of their individual applicants. In total, the responding insurers reported selling

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[24] Throughout this discussion, small group risk classification statistics are provided only when the related survey response was meaningful. Note also that small group underwriting varies. Some insurers risk-classify each small group member individually; covering some members on a standard basis, requiring exclusion waivers for others, and possibly refusing to cover others. Other insurers look at the small group as a whole and either underwrite the group entirely or not at all. The statistics reported here reflect the former practice.

**Table 2-5.—Risk Classification by Commercial Health Insurers: Common Conditions Requiring a Higher Premium, Exclusion Waiver, or Denial**

| Higher premium | Exclusion waiver | Denial |
|---|---|---|
| Allergies | Cataract | AIDS |
| Asthma | Gallstones | Ulcerative colitis |
| Back strain | Fibroid tumor (uterus) | Cirrhosis of liver |
| Hypertension (controlled) | Hernia (hiatal/inguinal) | Diabetes mellitus |
| Arthritis | Migraine headaches | Leukemia |
| Gout | Pelvic inflammatory disease | Schizophrenia |
| Glaucoma | Chronic otitis media (recent) | Hypertension (uncontrolled) |
| Obesity | Spine/back disorders | Emphysema |
| Psychoneurosis (mild) | Hemorrhoids | Stroke |
| Kidney stones | Knee impairment | Obesity (severe) |
| Emphysema (mild to moderate) | Asthma | Angina (severe) |
| Alcoholism/drug use | Allergies | Coronary artery disease |
| Heart murmur | Varicose veins | Epilepsy |
| Peptic ulcer | Sinusitis, chronic or severe | Lupus |
| Colitis | Fractures | Alcoholism/drug abuse |

SOURCE: Office of Technology Assessment, 1988.

more than 1.5 million new standard individual policies each year; appproximately 73 percent of their individual applicants are classified as standard (table 2-6, figure 2-1).

Almost two-thirds (24 of 38) of the respondents underwriting small groups also cover 60 to 100 percent of group members on a standard basis. Overall, approximately three-quarters of small

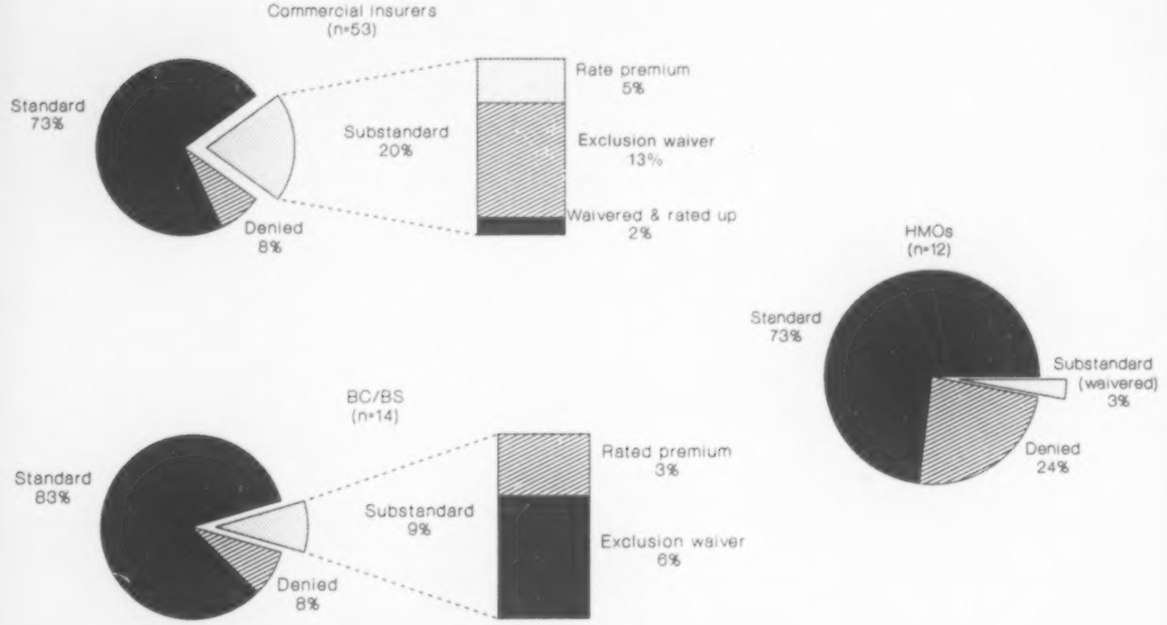
**Table 2-6.—Underwriting by Commercial Health Insurers: Risk Classification of Individual and Small Group Applicants**

| | Individuals | | Small group | |
|---|---|---|---|---|
| Percent of applicants | Number of companies (n=61) | Percent of companies[a] | Number of companies (n=38) | Percent of companies[a] |
| **Standard:** | | | | |
| Never used | 0 | — | 0 | — |
| 1 to 19% | 0 | — | 0 | — |
| 20 to 39% | 1 | 2% | 1 | 3% |
| 40 to 59% | 7 | 11 | 1 | 3 |
| 60 to 79% | 26 | 43 | 7 | 18 |
| 80 to 100% | 20 | 33 | 17 | 45 |
| Not available | 7 | 11 | 12 | 32 |
| Total | 61 | 100% | 38 | 100% |
| **Substandard:** | | | | |
| *Exclusion waiver:* | | | | |
| Never used | 3 | 5% | 14 | 37% |
| 1 to 19% | 35 | 57 | 10 | 26 |
| 20 to 39% | 13 | 21 | 2 | 5 |
| 40 to 59% | 1 | 2 | 0 | — |
| 60 to 79% | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — |
| Not available | 9 | 15 | 12 | 32 |
| Total | 61 | 100% | 38 | 100% |
| *Rated premium:* | | | | |
| Never used | 13 | 21% | 20 | 53% |
| 1 to 19% | 35 | 57 | 5 | 13 |
| 20 to 39% | 3 | 5 | 1 | 3 |
| 40 to 59% | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — |
| Not available | 10 | 16 | 12 | 32 |
| Total | 61 | 100% | 38 | 100% |
| *Exclusion waiver and rated premium:* | | | | |
| Never used | 16 | 26% | 22 | 58% |
| 1 to 19% | 33 | 54 | 3 | 8 |
| 20 to 39% | 1 | 2 | 1 | 3 |
| 40 to 59% | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — |
| Not available | 11 | 18 | 12 | 32 |
| Total | 61 | 100% | 38 | 100% |
| **Rejected:** | | | | |
| Never used | 1 | 2% | 0 | — |
| 1 to 19% | 52 | 85 | 20 | 53% |
| 20 to 39% | 1 | 2 | 7 | 18 |
| 40 to 59% | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — |
| Not available | 7 | 11 | 11 | 29 |
| Total | 61 | 100% | 38 | 100% |

[a] Percentages may not total 100 due to rounding.

SOURCE: Office of Technology Assessment, 1988.

Figure 2-1.—Risk Classification in Individual Health Insurance: Estimated Proportions of Standard, Substandard, and Denied Applicants[a b c]



[a] Only those respondents reporting complete risk classification data were included.

[b] Proportions were estimated by dividing the respondents' total number of applicants in each risk class by their total number of applications.

[c] Percentages may not total 100 due to rounding.

SOURCE: Office of Technology Assessment, 1988.

group applicants to companies that underwrite each group member individually are offered standard coverage.

Substandard policies include an exclusion waiver, a rated premium, or both. About 413,000 individual applicants were offered coverage on this basis by the responding insurers, or 20 percent of completed applications. The small group insurers offered substandard coverage to approximately 15 percent of their applicants (figure 2-1).

Exclusion waivers may temporarily or permanently exclude a medical condition from coverage. The exclusion may be for a specific condition, such as gallstones, or for an entire organ system, such as reproductive disorders. Permanent waivers usually exclude from coverage chronic conditions that are moderately costly and without life-threatening implications. Temporary waivers generally involve acute conditions that are short-term in nature, such as fractures or some minor surgery. More than half of the responding insurers (35 of 61) reported that 1 to 19 percent of their individual applicants carry an exclusion waiver. Thirteen (21 percent) required exclusions for 20 to 39 percent of their applicants (table 2-6).

Thirty-two percent of the small group insurers (12 of 38) required exclusion waivers for 1 to 39 percent of small group members applying for coverage.

Thirty-five insurers (57 percent) reported that the increased risk associated with 1 to 19 percent of their applicants required a rated premium. The additional premiums usually range from 25 to 100 percent of the standard premium, although some insurers will use higher ratings (123). Thirteen companies (21 percent) never rate-up applicants.

Rated conditions do not differ significantly from those that insurers may exclude; in general, higher premiums are required for chronic but moderately severe conditions (e.g., asthma, glaucoma). Whether a condition is excluded or rated is a matter of company pricing policy and strategy. Sometimes the insurer does both.

Most of the responding insurers (56 percent) noted that some policies may require an exclusion and rated premium; 1 to 22 percent of applicants are underwritten this way.

Eight percent of individual applicants were denied coverage by the responding insurers; approximately 164,000 individuals each year. Most companies (54 percent) deny coverage to less than 10 percent of their applicants; 31 percent deny coverage to between 10 and 19 percent. Coverage may be denied for serious medical reasons or "because an applicant is clearly outside a particular company's parameter of acceptable risks for occupational or financial reasons" (123). Most insurers deny any applicant whose probability of disease exceeds three times the average for his sex and age.

More than half the small group insurers (20 of 38) deny 1 to 19 percent of small group applicants. Overall, approximately 10 percent of small group applicants to companies that underwrite each group member individually are denied coverage.

Insurability is not just a matter of health status; several factors are key to the underwriter's decision to deny an application, to exclude a condition, or to rate up an applicant. The survey results indicate that other factors besides ill health can seriously hamper access to health coverage for nongroup individuals and their family members (table 2-7).

When asked to indicate which nonmedical underwriting factors could affect an application's acceptance, commercial insurers most commonly cited dangerous health habits (e.g., drug abuse), illegal or unethical behavior (e.g., criminal business practices), age, and occupation.

Drug abuse, and other health endangering habits, perhaps better categorized as significant predictors of health status, were considered of critical importance by 57 (93 percent) responding companies; indeed, many emphasized that drug abusers are uninsurable. Nearly three-quarters (44 of 61) of those responding also considered "illegal or unethical behavior" incompatible with insurability. This probably reflects the great sensitivity of the industry to fraud. Age and occupation, though reported by roughly one-third to be key to a proposed insured's acceptance or rejection, were more often noted to influence coverage limits or premiums.

Healthy habits, such as non-smoking, were rated "important" by more than half of the insurers (34 of 61), an indication of the increasingly common use of premium credits for nonsmokers. Dangerous avocations, such as race car driving or hang gliding, were considered either "very important" or "important" to almost 80 percent (48 of 61) of those surveyed. Rather than deny coverage to applicants with risky hobbies, most underwriters choose to limit only the insurer's responsibility for related accidents.

The survey results also show that financial status plays a key role in health insurance underwriting. Sixteen percent (10 of 61) of those responding said financial factors alone could affect acceptance of an application; another 43 percent (26 of 61) considered it "important" to coverage limits and premium levels. Some insurers may establish minimum income requirements for certain types of medical expense policies in order to avoid early lapses caused by the insured's inability to afford the premium (123).

Many respondents reported requiring financial and personal investigations. (See "Sources of Medical Information," table 2-12.) Although 25 percent (15 of 61) of the respondents never require an investigation, 16 percent (10 of 61) investigate one-fourth or more of their applicants. Two companies reported that financial or personal checks are done on every individual applicant. More than one-third of the small group insurers (13 of 38) also require similar checks on applicants. One company requires investigations of all its small group applicants. Most commonly, these inspections are credit and motor vehicle record checks, but insurers also rely on inspection agencies to verify health information reported in the appli-

**Table 2-7.—Individual Underwriting by Commercial Health Insurers: The Importance of Non-Medical Factors**

| Underwriting factor (n=61)[b] | Very important[a] | | Important | | Unimportant | | Never used | |
|---|---|---|---|---|---|---|---|---|
| | Number | Percent[c] | Number | Percent[c] | Number | Percent[c] | Number | Percent[c] |
| 1. Age | 23 | 38% | 29 | 48% | 6 | 10% | 3 | 5% |
| 2. Type of occupation | 18 | 30 | 29 | 48 | 11 | 18 | 3 | 5 |
| 3. Avocation (e.g., race car driving) | 9 | 15 | 39 | 64 | 9 | 15 | 4 | 7 |
| 4. Financial status | 10 | 16 | 26 | 43 | 20 | 33 | 5 | 8 |
| 5. Health endangering personal habits (e.g., drug abuse) | 57 | 93 | 3 | 5 | 0 | — | 1 | 2 |
| 6. Health enhancing personal behavior (e.g., non-smoking) | 6 | 10 | 34 | 56 | 9 | 15 | 12 | 20 |
| 7. Illegal or unethical behavior | 44 | 72 | 13 | 21 | 2 | 3 | 2 | 3 |
| 8. Place of residence | 3 | 5 | 13 | 21 | 21 | 34 | 24 | 39 |
| 9. Sexual orientation | 1 | 2 | 4 | 7 | 13 | 21 | 43 | 70 |

[a] Definitions: *Very important*—Critical to underwriting process; can affect acceptance/rejection.
*Important*—Always considered but will never by itself affect acceptance/rejection. It may, however, influence coverage limits (e.g., exclusions or waiting period) and/or premium.
*Unimportant*—Rarely affects acceptance/rejection, coverage limits, or premium—unless in conjunction with other more important factors.
*Never used*—Never considered.

[b] One company did not respond to this question.

[c] Row percentages may not total 100 due to rounding.

SOURCE: Office of Technology Assessment, 1988.

cation and even information on sexual orientation (see below).

Although close to 40 percent (24 of 61) of the commercial insurers never use place of residence in underwriting, more than one-quarter (16 of 61) consider it very "important" or "important." Another 34 percent (21 of 61) reported that residence may influence underwriting determinations when considered in conjunction with other more important risk factors. Several carriers noted that their concern over place of residence was due to insurance fraud that was known to occur in certain localities. Others indicated that use of place of residence in setting premiums is a result of regional variations in health care costs. Among the 31 respondents who tested for exposure to the AIDS virus, 3 (10 percent) required HIV screening of all applicants residing in areas of high AIDS prevalence.

Seventy percent (43 of 61) of the respondents indicated that sexual orientation is never used in underwriting. However, contrary to the 1987 National Association of Insurance Commissioner (NAIC) guidelines (212) recommending against using sexual orientation in underwriting, 5 companies considered it "very important" or "important" (i.e., affecting coverage, premiums, or possibly acceptance), and another 13 ranked it as "unimportant" (i.e., not affecting insurability unless present with other more important factors).[25] [26] In addition, three companies reported requesting an APS or physical exam based on sexual orientation.

It is unclear how insurers ascertain an applicant's sexual preference. Most (48 of 61) of the respondents provided samples of their health insurance applications, none of which included any questions concerning sexual orientation or lifestyle. One manager of a firm which specializes in insurance paramedical exams reported seeing references to an applicant's homosexuality in attending physician statements. Three insurers, in conversations with OTA, noted using indirect approaches or inspection agencies to confirm "suspicions of homosexuality" by, for example, interviewing a proposed insured's neighbors. (The NAIC guidelines, referred to above, also advise that "insurance support organizations shall be directed by insurers not to investigate, directly or indirectly, the sexual orientation of an applicant or beneficiary".) (212)

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[25] In July 1987, the NAIC issued a proposed bulletin stating that "sexual orientation may not be used in the underwriting process or in the determination of insurability." At least nine States (California, Colorado, Delaware, Florida, Iowa, Oregon, South Dakota, Texas, and Wisconsin) have barred using sexual orientation in underwriting or in the determination of insurability, premiums, terms of coverage, or renewals (212).

[26] These 18 companies hold approximately 10 percent of the individual, commercial health insurance market; 5 are among the 25 largest in the country (20).

**Blue Cross/Blue Shield Plans.**—Although BC/BS plans do not screen for high-risk applicants as exhaustively as do commercial carriers, the risk classification that is used once a high-risk applicant is identified varies little from the approach used by commercial carriers. Medical conditions that commonly require a rated premium, exclusion waiver, or are wholly uninsurable by commercial insurers are similarly classified by the nonopen, responding plans (see table 2-5).

Open enrollment programs do not classify applicants by risk in the usual sense, although they typically provide fewer comprehensive benefits and may require open enrollment subscribers to pay higher premiums than other applicants for identical coverage. Open enrollment coverage usually requires waiting periods before initial benefits may be paid for preexisting conditions and may exclude preexisting conditions.

Fourteen of fifteen responding plans reported receiving a total of 401,500 individual applications annually.[27]

Most BC/BS applicants for individual coverage are classified as standard. Thirteen plans (86 percent) provided standard coverage to 60 to 100 percent of their nongroup applicants; the other two plans classified 40 to 59 percent as standard (table 2-8). In total, respondents reported selling approximately 332,000 new nongroup standard policies each year. Eighty-three percent of their individual applicants were classified as standard (figure 2-1).

Sixty to 100 percent of small group applicants were also accepted as standard by half the plans (7 of 14) and up to 25 percent were denied.

Each year about 37,000 individual applicants are offered substandard coverage by the responding plans; 9 percent of those completing applications. Exclusion riders, rather than rated premiums, are more commonly used in BC/BS individual policies. Eight plans (53 percent) reported requiring an exclusion for up to 39 percent of their nongroup applicants, while only four plans (27 percent) charged higher premiums for less than 20 percent of applicants. One continuous open enrollment plan required exclusion waivers for 27 percent of its applicants.

Only two plans (14 percent) reported ever requiring exclusions or rated premiums for small group members.

The respondents (open and nonopen enrollment combined) refused coverage to 8 percent of their individual applicants. Denial rates range from 0 (for open enrollment plans) to 35 percent (table 2-8).

Underwriting by BC/BS plans appears to be considerably less complex than that done by the commercials. Not only is medical evaluation of applicants much less exhaustive, but also far fewer factors are weighed. The survey questionnaire asked the plans to try to quantify the effects of a number of factors on an applicant's insurability; that is, to estimate the proportion of applicants who are either denied coverage or offered only limited coverage or an increased premium because of medical condition, age, poor health habits, place of residence, etc. (table 2-9).

The responses to these questions indicate that BC/BS insurability is almost purely a question of medical condition. All but the four continuous open enrollment plans reject some applicants in poor health, with medically-based denial rates ranging from 7 to 33 percent. Close to half the plans (7 of 15) also reported denying nongroup applications because of alcohol or drug abuse histories (table 2-9).[28]

In many BC/BS plans, regardless of open enrollment policy, any known existing disease or impairment, whether acute or chronic, may not be covered, or a waiting period may be required. Nine of the 15 plans (60 percent) used such limits because of the medical condition of 5 to 27 percent of their applicants.

Nearly three-quarters (11 of 15) of the responding plans never "rate-up" individual premiums because of medical condition. Of the four plans that

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[27] One plan did not furnish nongroup application data. Small group application statistics were unavailable from most of the respondents.

[28] BC/BS plans may deny coverage to applicants residing outside their service area.

### Table 2-8.—Blue Cross/Blue Shield Plans: Risk Classification of Individual and Small Group Applicants

| | Individuals | | Small groups | |
|---|---|---|---|---|
| Percent of applicants | Number of plans (n=15) | Percent of plans | Number of plans (n=14) | Percent of plans |
| **Standard:** | | | | |
| Never used | 0 | — | 0 | — |
| 1 to 19% | 0 | — | 0 | — |
| 20 to 39% | 0 | — | 1 | 7% |
| 40 to 59% | 2 | 13% | 0 | — |
| 60 to 79% | 8 | 53 | 1 | 7 |
| 80 to 100% | 5 | 33 | 6 | 43 |
| Not available | 0 | — | 6 | 43 |
| Total | 15 | 100% | 14 | 100% |
| **Substandard:** | | | | |
| *Exclusion waiver:* | | | | |
| Never used | 7 | 47% | 7 | 50% |
| 1 to 19% | 6 | 40 | 2 | 14 |
| 20 to 39% | 2 | 13 | 0 | — |
| 40 to 59% | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — |
| Not available | 0 | — | 5 | 36 |
| Total | 15 | 100% | 14 | 100% |
| *Rated premium:* | | | | |
| Never used | 11 | 73% | 8 | 50% |
| 1 to 19% | 4 | 27 | 0 | — |
| 20 to 39% | 0 | — | 0 | — |
| 40 to 59% | 0 | — | 1 | 7 |
| 60 to 79% | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — |
| Not available | 0 | — | 5 | 36 |
| Total | 15 | 100% | 14 | 100% |
| **Rejected:** | | | | |
| Never used | 3 | 20% | 1 | 7% |
| 1 to 19% | 7 | 47 | 4 | 29 |
| 20 to 39% | 5 | 33 | 3 | 21 |
| 40 to 59% | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — |
| Not available | 0 | — | 6 | 43 |
| Total | 15 | 100% | 14 | 100% |

SOURCE: Office of Technology Assessment, 1988.

do, 2 to 19 percent of their individual applicants are affected. All the nongroup premium rates are age-based by four plans and affected by place of residence by two plans (i.e., because of regional variations in health costs.) More than half the applicants at two other plans are given nonsmoker discounts.

No BC/BS plan reported using sexual orientation in underwriting. However, one plan did originally report modifying nongroup premiums on this basis (for 3 percent of their applicants). When questioned by OTA as to how sexual orientation is identified, the plan underwriter explained that they had interpreted the term to mean sex (i.e., male or female).

Only one respondent requested routine financial or personal investigations, inspecting 10 percent of its applicants for nongroup coverage (See "Sources of Medical Information," table 2-15.)

**Table 2-9.—Individual Underwriting by Blue Cross/Blue Shield Plans: The Importance of Medical and Other Factors**

| | Reject applicant (n = 15) | | Limit coverage (n = 15) | | Increase (decrease) premium rates (n = 15) | |
|---|---|---|---|---|---|---|
| Percent of non-group applicants[a] | Number of plans | Percent of plans[b] | Number of plans | Percent of plans[b] | Number of plans | Percent of plans[b] |
| **Medical condition:** | | | | | | |
| Never used | 4 | 27% | 5 | 33% | 8 | 53% |
| 1 to 9% | 2 | 13 | 3 | 20 | 2 | 13 |
| 10 to 19% | 4 | 27 | 4 | 27 | 2 | 13 |
| 20 to 29% | 4 | 27 | 2 | 13 | 0 | — |
| 30 to 39% | 1 | 7 | 0 | — | 0 | — |
| Not applicable | 0 | — | 1 | 7 | 3 | 20 |
| Total | 15 | 100% | 15 | 100% | 15 | 100% |
| **Age:** | | | | | | |
| Never used | 15 | 100% | 14 | 93% | 8 | 53% |
| 100% | 0 | — | 0 | — | 4 | 27 |
| Not applicable | 0 | — | 1 | 7 | 3 | 20 |
| Total | 15 | 100% | 15 | 100% | 15 | 100% |
| **Dangerous habits (e.g., drug abuse):** | | | | | | |
| Never used | 6 | 40% | 12 | 80% | 11 | 73% |
| 1 to 9% | 6 | 40 | 0 | — | 0 | — |
| 10 to 19% | 0 | — | 1 | 7 | 0 | — |
| 20 to 29% | 1 | 7 | 0 | — | 0 | — |
| Not applicable | 2 | 13 | 2 | 13 | 4 | 27 |
| Total | 15 | 100% | 15 | 100% | 15 | 100% |
| **Place of residence:** | | | | | | |
| Never used | 13 | 87% | 14 | 93% | 10 | 67% |
| 1 to 9% | 2 | 13 | 0 | — | 0 | — |
| 90 to 100% | 0 | — | 0 | — | 2 | 13 |
| Not applicable | 0 | — | 1 | 7 | 3 | 20 |
| Total | 15 | 100% | 15 | 100% | 15 | 100% |
| **Healthy habits (e.g., non-smoking):** | | | | | | |
| Never used | | | | | 10 | 67% |
| 50 to 69% | | | | | 1 | 7 |
| 70 to 79% | —NA— | | —NA— | | 1 | 7 |
| Not applicable | | | | | 3 | 20 |
| Total | | | | | 15 | 100% |

[a]Intervals with no reported frequency are omitted.
[b]Percentages may not total 100 due to rounding.

SOURCE: Office of Technology Assessment, 1988.

**Health Maintenance Organizations.**[29]—HMO risk classification often differs from the traditional commercial and BC/BS insurers' approaches. Federally qualified plans are restricted to either accepting non-Medicare applicants at a community rate or denying membership altogether. Exclusions, rated premiums, and waiting periods are prohibited. Some States have similar requirements. However, HMO underwriting does reflect traditional practice with respect to medically uninsurable conditions. The responding HMOs were no more willing to underwrite high-risk applicants than the commercial insurers or BC/BS plans. When asked which conditions the HMO considered uninsurable, the plans' responses mirrored those given by the traditional insurers (see table 2-5).

In total, 12 of 15 HMOs reported receiving approximately 57,900 self-pay (i.e., individual) applications each year and enrolling 73 percent on a standard basis. Standard acceptance rates ranged from 49 percent at one plan to 100 percent at two plans required by State law to hold open enrollment (tables 2-10, figure 2-1).[30]

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[29] Most of the responding HMOs were unable to provide small group risk classification data.

Only two HMOs (13 percent) reported enrolling individual members on a substandard basis; both required exclusion waivers for 10 to 15 percent of their applicants. (One of these plans was not federally qualified, the other was but had a nonfederally qualified subsidiary.)

Rejection rates for the responding HMOs were high relative to the commercial and BC/BS insurers. Eleven of fifteen HMOs denied membership to 20 to 59 percent of their individual applicants. In total, 12 responding HMOs refused membership to approximately 13,700 self-pay applicants annually, 24 percent of their self-pay applicants. In contrast, the commercials and BC/BS plans both denied 8 percent of self-pay applicants. It may be that HMOs receive a greater proportion of high-risk applicants because of their comprehensive coverage and community rating practices. In addition, the Federal qualification requirements and State regulations that restrict HMO use of exclusions and rated premiums may limit the ability of the plans to underwrite many individuals. Clearly, further study is warranted in order to understand these differences.

**Table 2-10.—Health Maintenance Organizations: Risk Classification of Individual Applicants[a]**

| Percent of applicants | Number of HMOs (n = 15) | Percent of HMOs[b] |
|---|---|---|
| **Standard:** | | |
| Never used | 0 | — |
| 1 to 19% | 0 | — |
| 20 to 39% | 0 | — |
| 40 to 59% | 1 | 7% |
| 60 to 79% | 6 | 40 |
| 80 to 100% | 6 | 40 |
| Not available | 2 | 13 |
| Total | 15 | 100% |
| **Substandard:** | | |
| *Exclusion waiver:* | | |
| Never used | 11 | 73% |
| 1 to 19% | 2 | 13 |
| 20 to 39% | 0 | — |
| 40 to 59% | 0 | — |
| 60 to 79% | 0 | — |
| 80 to 100% | 0 | — |
| Not available | 2 | 13 |
| Total | 15 | 100% |
| *Rated premium:* | | |
| Never used | 13 | 87% |
| Not available | 2 | 13 |
| Total | 15 | 100% |
| **Rejected:** | | |
| Never used | 2 | 13% |
| 1 to 19% | 1 | 7 |
| 20 to 39% | 9 | 60 |
| 40 to 59% | 1 | 7 |
| 60 to 79% | 0 | — |
| 80 to 100% | 0 | — |
| Not available | 2 | 13 |
| Total | 15 | 100% |

[a] Small group data are omitted due to poor response to this question.
[b] Percentages may not total 100 due to rounding.

SOURCE: Office of Technology Assessment, 1988.

Access to HMO self-pay membership is fundamentally a matter of health status. All but three of the respondents (81 percent) reported that medical conditions can affect either the applicant's acceptance, premium rate, or scope of benefits. The three plans that never consider the applicant's health are located in a State that mandates HMOs to hold an annual 30-day open enrollment period (without medical screening); due to possible adverse selection, this is the only time these HMOs are willing to enroll individuals (table 2-11).

Age, type of occupation, health enhancing behavior (e.g., nonsmoking), and sexual orientation are also considered key to insurability by 19 percent or more of the respondents. It is not clear how sexual orientation is identified by the four plans that use it in underwriting. No surveyed plan reported using personal inspection agencies, and none of the provided enrollment applications included any relevant lifestyle questions. The National Association of HMO Regulators (NAHMOR), which serves a role similar to that of the NAIC, has not yet taken a position on the appropriateness of using sexual orientation in underwriting (208). (See previous discussion of the NAIC recommendations.)

## Sources of Medical Information

**Commercial Insurers.**—The underwriter's objective is to know as much about the applicant's health status as the applicant. Any health insurance policy based on medical underwriting requires the applicant (and each family member) to complete a health history questionnaire. (An ex-

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[30] Statistics for some national plans may represent only one locale.

Table 2-11.—Individual Underwriting by Health Maintenance Organizations: The Importance of Medical and Other Factors

| Underwriting factor (n=16)[b] | Very important[a] | | Important | | Unimportant | | Never used | |
|---|---|---|---|---|---|---|---|---|
| | Number of HMOs | Percent of HMOs[c] | Number of HMOs | Percent of HMOs[c] | Number of HMOs | Percent of HMOs[c] | Number of HMOs | Percent of HMOs[c] |
| 1. Medical condition | 10 | 63% | 2 | 13% | 1 | 6% | 3 | 19% |
| 2. Age | 1 | 6 | 6 | 38 | 2 | 13 | 7 | 44 |
| 3. Type of occupation | 0 | — | 3 | 19 | 3 | 19 | 10 | 63 |
| 4. Avocation (e.g., race car driving) | 0 | — | 1 | 6 | 3 | 19 | 12 | 75 |
| 5. Financial status | 1 | 6 | 0 | — | 4 | 25 | 11 | 69 |
| 6. Health enhancing personal behavior (e.g., nonsmoking) | 2 | 13 | 3 | 19 | 2 | 13 | 9 | 56 |
| 7. Illegal or unethical behavior | 0 | — | 2 | 13 | 4 | 25 | 10 | 63 |
| 8. Place of residence | 1 | 6 | 1 | 6 | 1 | 6 | 13 | 81 |
| 9. Sexual orientation | 0 | — | 3 | 19 | 1 | 6 | 12 | 75 |

[a] Definitions: *Very Important*—Critical to underwriting process; can affect acceptance/rejection.
*Important*—Always considered but will never by itself affect acceptance/rejection. It may, however, influence coverage limits (e.g., exclusions or waiting period) and/or premium.
*Unimportant*—Rarely affects acceptance/rejection, coverage limits, or premium—unless in conjunction with other more important factors.
*Never used*—Never considered.

[b] Includes one HMO that does not underwrite individuals but accepts individually underwritten groups.

[c] Row percentages may not total 100 due to rounding.

SOURCE: Office of Technology Assessment, 1988.

ample is presented in figure 2-2). As evidenced by the survey responses, company policies vary considerably with respect to the proportion of applicants required to provide further evidence of their health status, either via an attending physician statement, physical exam, blood and urine tests, and/or financial or personal investigations (table 2-12).

*Attending Physician Statements (APS).*—Individually underwritten health insurance applicants are always asked to supply the name and address of their personal physician and their doctor may be asked to complete a medical history in a standard APS form (although physicians sometimes send the insurer a photocopy of the applicant's medical record instead). The standard APS questionnaire calls for a complete description of the patient's complaints, any abnormal findings including laboratory and other test results, treatment or operation, present condition if known, and other medical information that has a bearing on the applicant's health, such as smoking or alcohol use. For children under 6 months of age, additional information may be requested regarding birth weight and the presence of any disease or abnormality. (An example of an APS is presented in figure 2-3.)

Beyond the health data provided directly in the insurance application, the APS is the most common supplemental source of medical underwriting information. Overall, the responding insurers reported requiring an APS for 20 percent of their individual applicants, a total of 446,000 physician statements each year. Members of small and large groups are often required to provide an APS as well.[31]

More than half the responding small group insurers (20 of 38) require an APS for 10 percent or more of their applicants and 13 of 27 large group insurers (48 percent) request an APS of 1 to 75 percent of their applicants. Overall, 18 percent of the respondents' small group applicants were required to furnish an APS (table 2-12, figure 2-4).

The APS is clearly the insurer's principal source of testing data, since it often includes recent test results as well as x-rays, electrocardiograms, and pathology reports. Although close to two-thirds of the respondents (38 of 61) require physician statements of 20 to 79 percent of their individual applicants, more than three-quarters (47 of 61) test only 5 percent or less. Therefore, testing ordered by the applicant's personal physician appears to be as critical to insurability as tests initiated by the insurer (table 2-12, figure 2-4).

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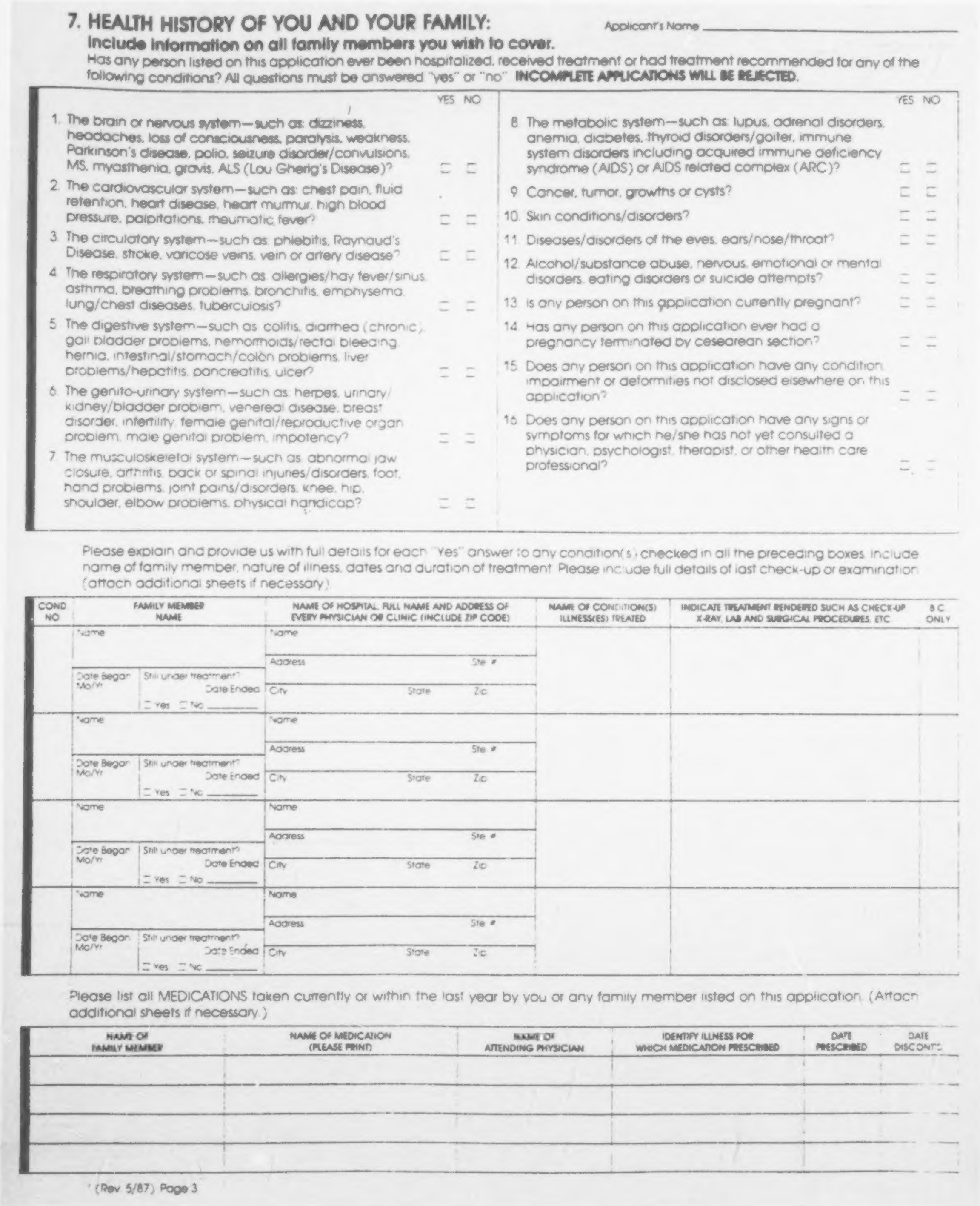
[31] The discussion of large groups throughout this report refers primarily to employees who are eligible for group health insurance but choose not to sign up until after the normal enrollment period (i.e., late applicants).

Figure 2-2.—Typical Health History Questionnaire in a Commercial Health Insurance Application



**7. HEALTH HISTORY OF YOU AND YOUR FAMILY:** Applicant's Name ____________________

**Include information on all family members you wish to cover.**

Has any person listed on this application ever been hospitalized, received treatment or had treatment recommended for any of the following conditions? All questions must be answered "yes" or "no" **INCOMPLETE APPLICATIONS WILL BE REJECTED.**

| | YES | NO |
|---|---|---|
| 1. The brain or nervous system—such as: dizziness, headaches, loss of consciousness, paralysis, weakness, Parkinson's disease, polio, seizure disorder/convulsions, MS, myasthenia, gravis, ALS (Lou Gherig's Disease)? | ☐ | ☐ |
| 2. The cardiovascular system—such as: chest pain, fluid retention, heart disease, heart murmur, high blood pressure, palpitations, rheumatic fever? | ☐ | ☐ |
| 3. The circulatory system—such as phlebitis, Raynaud's Disease, stroke, varicose veins, vein or artery disease? | ☐ | ☐ |
| 4. The respiratory system—such as allergies/hay fever/sinus, asthma, breathing problems, bronchitis, emphysema, lung/chest diseases, tuberculosis? | ☐ | ☐ |
| 5. The digestive system—such as colitis, diarrhea (chronic), gall bladder problems, hemorrhoids/rectal bleeding, hernia, intestinal/stomach/colon problems, liver problems/hepatitis, pancreatitis, ulcer? | ☐ | ☐ |
| 6. The genito-urinary system—such as herpes, urinary/kidney/bladder problem, venereal disease, breast disorder, infertility, female genital/reproductive organ problem, male genital problem, impotency? | ☐ | ☐ |
| 7. The musculoskeletal system—such as abnormal jaw closure, arthritis, back or spinal injuries/disorders, foot, hand problems, joint pains/disorders, knee, hip, shoulder, elbow problems, physical handicap? | ☐ | ☐ |
| 8. The metabolic system—such as lupus, adrenal disorders, anemia, diabetes, thyroid disorders/goiter, immune system disorders including acquired immune deficiency syndrome (AIDS) or AIDS related complex (ARC)? | ☐ | ☐ |
| 9. Cancer, tumor, growths or cysts? | ☐ | ☐ |
| 10. Skin conditions/disorders? | ☐ | ☐ |
| 11. Diseases/disorders of the eyes, ears/nose/throat? | ☐ | ☐ |
| 12. Alcohol/substance abuse, nervous, emotional or mental disorders, eating disorders or suicide attempts? | ☐ | ☐ |
| 13. Is any person on this application currently pregnant? | ☐ | ☐ |
| 14. Has any person on this application ever had a pregnancy terminated by cesearean section? | ☐ | ☐ |
| 15. Does any person on this application have any condition, impairment or deformities not disclosed elsewhere on this application? | ☐ | ☐ |
| 16. Does any person on this application have any signs or symptoms for which he/she has not yet consulted a physician, psychologist, therapist, or other health care professional? | ☐ | ☐ |

Please explain and provide us with full details for each "Yes" answer to any condition(s) checked in all the preceding boxes. Include name of family member, nature of illness, dates and duration of treatment. Please include full details of last check-up or examination (attach additional sheets if necessary).

| COND NO | FAMILY MEMBER NAME | NAME OF HOSPITAL, FULL NAME AND ADDRESS OF EVERY PHYSICIAN OR CLINIC (INCLUDE ZIP CODE) | NAME OF CONDITION(S) ILLNESS(ES) TREATED | INDICATE TREATMENT RENDERED SUCH AS CHECK-UP X-RAY, LAB AND SURGICAL PROCEDURES, ETC | B C ONLY |
|---|---|---|---|---|---|
| | Name<br>Date Began Mo/Yr<br>Still under treatment? Date Ended<br>☐ Yes ☐ No ________ | Name<br>Address Ste #<br>City State Zip | | | |
| | Name<br>Date Began Mo/Yr<br>Still under treatment? Date Ended<br>☐ Yes ☐ No ________ | Name<br>Address Ste #<br>City State Zip | | | |
| | Name<br>Date Began Mo/Yr<br>Still under treatment? Date Ended<br>☐ Yes ☐ No ________ | Name<br>Address Ste #<br>City State Zip | | | |
| | Name<br>Date Began Mo/Yr<br>Still under treatment? Date Ended<br>☐ Yes ☐ No ________ | Name<br>Address Ste #<br>City State Zip | | | |

Please list all MEDICATIONS taken currently or within the last year by you or any family member listed on this application. (Attach additional sheets if necessary.)

| NAME OF FAMILY MEMBER | NAME OF MEDICATION (PLEASE PRINT) | NAME OF ATTENDING PHYSICIAN | IDENTIFY ILLNESS FOR WHICH MEDICATION PRESCRIBED | DATE PRESCRIBED | DATE DISCONT'D |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

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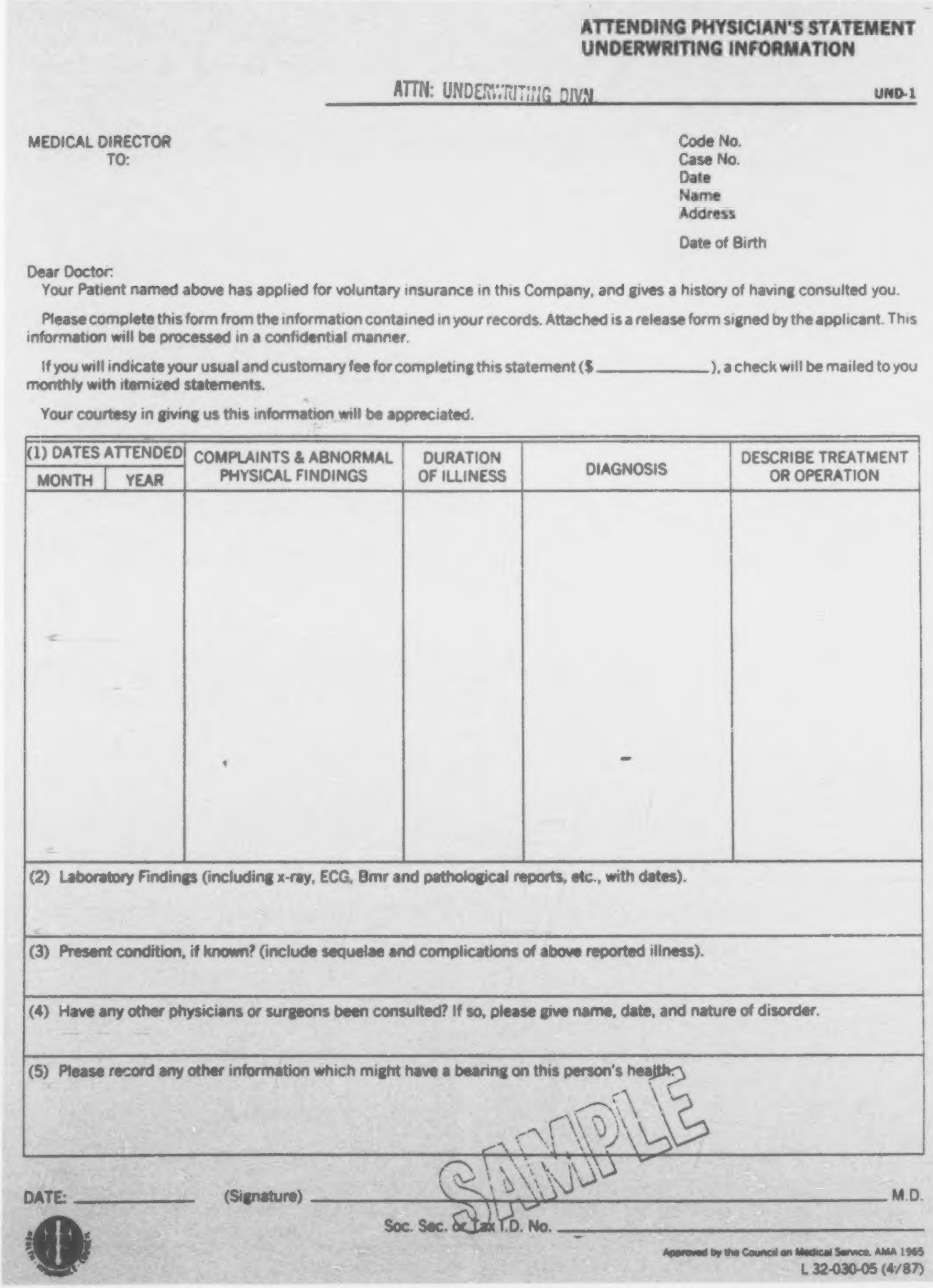
Figure 2-3.—Attending Physician's Statement Used for Commercial Health Insurance Applicants



**ATTENDING PHYSICIAN'S STATEMENT**
**UNDERWRITING INFORMATION**

ATTN: UNDERWRITING DIVN.

UND-1

MEDICAL DIRECTOR
TO:

Code No.
Case No.
Date
Name
Address

Date of Birth

Dear Doctor:

Your Patient named above has applied for voluntary insurance in this Company, and gives a history of having consulted you.

Please complete this form from the information contained in your records. Attached is a release form signed by the applicant. This information will be processed in a confidential manner.

If you will indicate your usual and customary fee for completing this statement ($ ____________ ), a check will be mailed to you monthly with itemized statements.

Your courtesy in giving us this information will be appreciated.

| (1) DATES ATTENDED | | COMPLAINTS & ABNORMAL PHYSICAL FINDINGS | DURATION OF ILLINESS | DIAGNOSIS | DESCRIBE TREATMENT OR OPERATION |
|---|---|---|---|---|---|
| MONTH | YEAR | | | | |
| | | | | | |

(2) Laboratory Findings (including x-ray, ECG, Bmr and pathological reports, etc., with dates).

(3) Present condition, if known? (include sequelae and complications of above reported illness).

(4) Have any other physicians or surgeons been consulted? If so, please give name, date, and nature of disorder.

(5) Please record any other information which might have a bearing on this person's health.

SAMPLE

DATE: ____________ (Signature) ________________________________ M.D.

Soc. Sec. or Tax I.D. No. ________________________

Approved by the Council on Medical Service, AMA 1965
L 32-030-05 (4/87)

Table 2-12.—Underwriting by Commercial Health Insurers: Health and Other Information Requirements

| Required underwriting information (percent of applicants) | Individual policies (n=61) | | Small group policies (n=38) | | Large group policies[a] (n=27) | |
|---|---|---|---|---|---|---|
| | Number of companies | Percent of companies[b] | Number of companies | Percent of companies[b] | Number of companies | Percent of companies[b] |
| **Attending physician statement (APS):** | | | | | | |
| Never used | 3 | 5% | 5 | 13% | 12 | 44% |
| 1 to 19% | 18 | 30 | 16 | 42 | 10 | 37 |
| 20 to 39% | 25 | 41 | 11 | 29 | 2 | 7 |
| 40 to 59% | 9 | 15 | 1 | 3 | 0 | — |
| 60 to 79% | 4 | 7 | 1 | 3 | 1 | 4 |
| 80 to 100% | 1 | 2 | 2 | 5 | 0 | — |
| Not available | 1 | 2 | 2 | 5 | 2 | 7 |
| Total | 61 | 100% | 38 | 100% | 27 | 100% |
| **Physical exam:** | | | | | | |
| Never used | 17 | 28% | 19 | 50% | 19 | 70% |
| 1 to 19% | 35 | 57 | 16 | 42 | 6 | 22 |
| 20 to 39% | 5 | 8 | 1 | 3 | 0 | — |
| 40 to 59% | 1 | 2 | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — | 0 | — |
| 80 to 100% | 2 | 3 | 0 | — | 0 | — |
| Not available | 1 | 2 | 2 | 5 | 2 | 7 |
| Total | 61 | 100% | 38 | 100% | 27 | 100% |
| **Blood or urine screens:** | | | | | | |
| Never used | 23 | 38% | 24 | 63% | 21 | 78% |
| 1 to 19% | 30 | 49 | 11 | 29 | 4 | 15 |
| 20 to 39% | 4 | 16 | 1 | 3 | 0 | — |
| 40 to 59% | 0 | — | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — | 0 | — |
| 80 to 100% | 2 | 3 | 0 | — | 0 | — |
| Not available | 2 | 3 | 2 | 5 | 2 | 7 |
| Total | 61 | 100% | 38 | 100% | 27 | 100% |
| **Financial or personal investigation:** | | | | | | |
| Never used | 15 | 25% | 22 | 58% | 22 | 81% |
| 1 to 19% | 33 | 54 | 12 | 32 | 2 | 7 |
| 20 to 39% | 5 | 8 | 1 | 3 | 1 | 4 |
| 40 to 59% | 1 | 2 | 0 | — | 0 | — |
| 60 to 79% | 2 | 3 | 0 | — | 0 | — |
| 80 to 100% | 4 | 7 | 1 | 3 | 0 | — |
| Not available | 1 | 2 | 2 | 5 | 2 | 7 |
| Total | 61 | 100% | 38 | 100% | 27 | 100% |

[a] Only late applicants to large groups are required to provide health and related information to obtain coverage.
[b] Percentages may not total 100 due to rounding.

SOURCE: Office of Technology Assessment, 1988.

There are a number of factors that lead the underwriter to require an APS. These are listed, in table 2-13, along with the number of survey respondents who use them as routine APS "triggers." The medical history revealed in the insurance application is the most common trigger; it was cited by every responding company that ever requires an APS. Seventy percent indicated that reports from the Medical Information Bureau (MIB), a databank of underwriting information shared by commercial insurers,[32] routinely trigger APS requests; 65 percent, that inspection reports (i.e., background checks) triggered a request for an APS; and 78 percent, that a history of drug abuse triggered APS requests. Older applicants are commonly required to provide further evidence of good health; 57 percent of the companies reported that APS requests are age-based. It is not surprising that older applicants are more closely scrutinized, as they are more likely to have health problems that are not reported on the application (123). As noted earlier, three companies reported using sexual orientation as a basis for requiring an APS.

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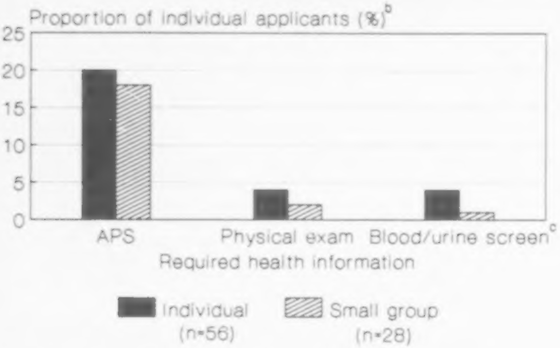
[32] The MIB is a non-profit association of more than 700 life and health insurers established in 1905 to facilitate sharing of underwriting information. Participating insurers report each applicant's significant medical findings (including test results) to the MIB and also routinely consult the MIB database for any relevant underwriting information on their current applicants.

**Figure 2-4.—Commercial Health Insurers[a] Estimated Proportion of Applicants Required To Have an APS, Physical Exam, or Blood/Urine Screen**



[a]Only those companies reporting complete data are included.
[b]The proportions were estimated by dividing the respondents' total number of applicants required to have an APS, physical, or blood/urine screen by their annual volume of applications.
[c]Blood/urine screening data do not include HIV screening.

SOURCE: Office of Technology Assessment, 1988.

Other reasons cited for requiring an APS included policy amount, blood transfusion before 1985, height/weight, previous claims history, occupation, and being uninsured for an extensive period.

*Physical Exams.*[33]—Physical examinations of individual health insurance applicants are much less common. Overall, only 4 percent were examined each year by the respondents, less than 94,000 nationwide. Seventeen (28 percent) of the 61 responding companies never require physicals for individual applicants. However, 15 (25 percent) did require at least 1 out of 10 applicants

**Table 2-13.—Individual Underwriting by Commercial Health Insurers: Reasons for Requiring an Attending Physician Statement or Physical Exam**

| | Attending physician statement (APS)[a] (n=60) | | Physical exam[b] (n=47) | |
|---|---|---|---|---|
| Reasons for requiring an APS or physical exam | Number of companies | Percent of companies | Number of companies | Percent of companies |
| Diagnosis reported on application | 60 | 100% | 42 | 89% |
| Attending physician statement (APS) | — | — | 44 | 94 |
| Medical Information Bureau report (MIB) | 42 | 70 | 33 | 70 |
| Drug abuse history | 47 | 78 | 25 | 53 |
| Inspection report | 39 | 65 | 29 | 62 |
| Age | 34 | 57 | 22 | 47 |
| Late group applicant | 12 | 20 | 4 | 9 |
| Geographic area | 4 | 7 | 1 | 2 |
| Sexual orientation | 3 | 5 | 2 | 4 |
| Sex | 2 | 3 | 0 | 0 |
| Other, including: | 16 | 27 | 21 | 45 |
| Policy amount | 3 | 5 | 8 | 17 |
| Height/weight | 2 | 3 | 4 | 9 |
| Blood transfusion before 1985 | 1 | 2 | — | — |
| Claims/medical history | 4 | 7 | 5 | 11 |
| Occupation | 1 | 2 | — | — |
| Extensive period of no insurance | 1 | 2 | 1 | 2 |
| No current physical | — | — | 1 | 2 |

[a]Includes two companies that only require an APS for members of individually underwritten groups.
[b]Includes three companies that only require physicals on members of individually underwritten groups.

SOURCE: Office of Technology Assessment, 1988.

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[33] Note that attending physician statements are furnished by the applicants' personal physicians while the physical exams described here are performed by physicians or paramedical professionals employed by the insurer.

to be examined by a physician or paramedical professional. In one company, every applicant must pass a physical; in another, 80 percent (table 2-12, figure 2-4).

Group insurance physicals are even less common. At least half of the responding group insurers never require a physical for either small or large group members. The majority of the small group insurers (14 of 17) that do require physicals examine 5 percent or less of their applicants. Overall, only 2 percent of the respondents' small group applicants were required to undergo a physical exam.

The reasons insurers cite for ordering a physical exam closely mirror those for requiring attending physician statements. In addition, APS findings themselves often lead the underwriter to request an exam for further clarification of the proposed insured's medical condition (table 2-13).

*Blood and Urine Screening.*—HIV screening may be the most discussed test, but it is only one of many tests ordered by commercial underwriters. Among the responding insurers who do test, standard panels of blood chemistries and urinalysis are most common. These standard panels of tests are characteristic of those commonly ordered by physicians as part of a general physical evaluation. In addition to the panels, many insurers reported ordering urine screens for drugs of abuse —such as cocaine and barbiturates—as well as for nicotine and prescription medications for diabetes, heart disease, and hypertension. The insurer's interest in prescription medication is twofold; first, to "catch" applicants who are less than straightforward in their health history questionnaire and, second, to determine whether known hypertensive applicants, for example, are conscientiously following prescribed treatment (table 2-14).

Insurance testing appears to be linked with physical exams. Close to 90 percent of commercial insurers requiring physicals (41 of 47) sometimes request that the applicant also be tested, and almost half of these insurers (22 of 47) uniformly test and examine equivalent proportions of their applicants. Only five companies reported performing physicals and never testing.

As in the case of physical examinations, routine testing is rare. In the aggregate, responding insurers reported requiring blood and/or urine screens from 4 percent of individual applicants, a total of approximately 83,000 individuals annually. Twenty-three (38 percent) respondents reported that individual applicants were never tested. Most companies that do test, do so infrequently; 24 (39 percent) respondents tested only 1 to 5 percent of their individual applicants. Eleven (18 percent) reported testing at least 1 out of 10 individual applicants. One company tested every applicant (table 2-12, figure 2-4).

Testing by the responding group insurers was especially uncommon; 63 percent of the small group (24 of 38) and 78 percent (21 of 27) of the large group carriers never require a blood or urine screen. The majority of group insurers that do screen require tests of less than 5 percent of their applicants. Overall, only 1 percent of the respondents' small group applicants were tested.

**Blue Cross/Blue Shield Plans.**—Although BC/BS plans have faced increasing competition from HMOs and other alternative insurers in recent years, the underwriting practices of many plans still reflect their past tradition of community rating and "taking all comers." Today, the majority of plans (69 percent) do not hold open enrollment periods (165). Nevertheless, relative to the commercial health insurers, the survey findings indicate that less scrutiny is given a BC/BS versus a commercial insurance applicant. Most BC/BS plans make no inquiries beyond the health history portion of the application and an attending physician statement. It is the rare BC/BS plan that demands a physical exam, blood chemistry, or urinalysis.

*Health History Questionnaire.*—All but one (i.e., a continuous open enrollment program) of the respondents require nongroup applicants to provide some health information prior to enrollment. BC/BS enrollment health history questionnaires vary in their comprehensiveness, but typically ask the applicant (and each family member) to indicate any history of receiving medical treatment or advice for a long list of diseases and disorders (see figure 2-1).

*Attending Physician Statements.*—The APS, along with the health history questionnaire, is the information foundation of BC/BS nongroup un-

Table 2-14.—Tests Commonly Ordered by Commercial Health Insurers

| Blood screens | | Urine screens | |
|---|---|---|---|
| Type of test | Common diagnostic use | Type of test | Common diagnostic use |
| I. *Diagnostic screens* | | I. *Diagnostic screens* | |
| Glucose | Diabetes | Microscopic analysis: | |
| Bun/creatinine | Kidney function | White blood cell count | Infection, cancer |
| Uric acid | Kidney stones | Red blood cell count | Anemia |
| Alkaline phosphatase | Liver function | Casts (granular, hyaline) | Kidney disorders |
| Bilirubin total | Gall bladder and liver function | Protein | Kidney disorders, hypertension |
| SGOT/SGPT | Hepatitis (alcoholic), liver function | Glucose | Diabetes |
| GGTP | Liver function | Specific gravity | Kidney function |
| Total protein | General health | | |
| Albumin | Liver function | II. *Prescription drug screens* | |
| Immunoglobulin | Immunodeficiency, infection | Oral hypoglycemics | Diabetes |
| Cholesterol | Circulatory disorders | Beta-blocker | Hypertension, coronary disease |
| Triglycerides | Circulatory disorders | Thiazide diuretics | Hypertension |
| HDL | Circulatory disorders | | |
| Chol/HDL chol ratio | Circulatory disorders | III. *Drug abuse screens* | |
| ELISA/ELISA/Western blot | HIV infection | Barbiturates | |
| T-Cell subset | HIV infection, immune system | Cocaine | |
| | | Nicotine | |

SOURCE: Office of Technology Assessment, 1988.

derwriting. Twelve of the fifteen responding plans (80 percent), including three that offer open enrollment, order an APS for at least 20 percent of their individual applicants. Four of these plans require physician statements for 40 percent or more of their applicants. The only two respondents that never ask nongroup applicants for an APS are traditional, continuous, open enrollment programs with significant market shares (table 2-15).

Generally, less information is required of group applicants to BC/BS plans. Six of the fourteen plans with small group coverage (43 percent) never request an APS; of the eight that do, 1 to 40 percent of applicants are affected. Only one-third (5 of 15) of the large group plans request an APS of some applicants.

The physician statements used by the respondents are similar to those used by commercial health insurers; physicians are asked to describe the applicant's recent health history and provide laboratory findings. Two BC/BS plans sometimes use diagnosis-specific (e.g., cardiac, hypertension) physician questionnaires that ask for extensive clarification of the applicant's health, including all relevant test findings (see figure 2-5).

A number of factors can lead a plan to require a physician statement. All the respondents said that the applicant's self-reported medical history can "trigger" an APS request. In addition, an APS is routinely ordered by 12 plans (86 percent) in cases of drug abuse history; 5 plans (36 percent), based on claims history; and 4 plans (29 percent), according to age (table 2-16).

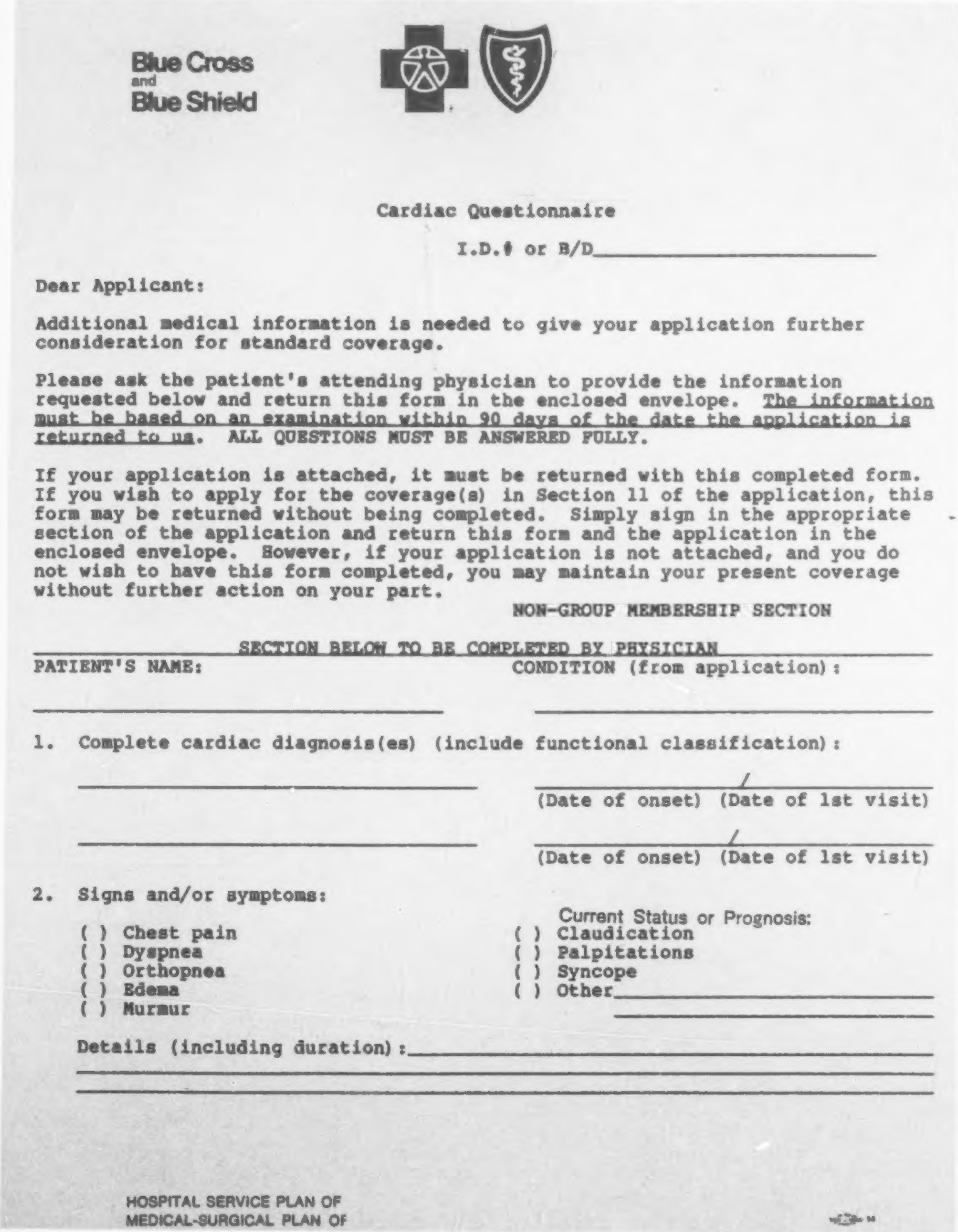
*Physical Exams.*—Only two plans reported requiring nongroup applicants to undergo a physical exam. One holds continuous open enrollment and examines close to one-third (30 percent) of nongroup enrollees. These physicals are done to evaluate whether the applicant may opt out of the open enrollment program and enroll in a more comprehensive plan. The other plan does not accept all applicants and examines, on average, 4 percent.

One plan orders physicals for 1 percent of small and 2 percent of large group applicants.

Medical history, age, and weight were reported as reasons for requiring a physical (table 2-16).

*Blood and Urine Screening.*—Blood and urine testing is very rare among BC/BS plans. Only one plan (7 percent) reported doing any screening of applicants; testing 4 percent of nongroup, 1 percent of small group, and 2 percent of large group applicants in conjunction with a physical exam. (A second plan reported intentions to test some

Figure 2-5.—Diagnosis-Specific Attending Physician Statement Used by a Blue Cross/Blue Shield Plan



Blue Cross
and
Blue Shield

Cardiac Questionnaire

I.D.# or B/D________________________

Dear Applicant:

Additional medical information is needed to give your application further consideration for standard coverage.

Please ask the patient's attending physician to provide the information requested below and return this form in the enclosed envelope. The information must be based on an examination within 90 days of the date the application is returned to us. ALL QUESTIONS MUST BE ANSWERED FULLY.

If your application is attached, it must be returned with this completed form. If you wish to apply for the coverage(s) in Section 11 of the application, this form may be returned without being completed. Simply sign in the appropriate section of the application and return this form and the application in the enclosed envelope. However, if your application is not attached, and you do not wish to have this form completed, you may maintain your present coverage without further action on your part.

NON-GROUP MEMBERSHIP SECTION

SECTION BELOW TO BE COMPLETED BY PHYSICIAN

PATIENT'S NAME: ________________________

CONDITION (from application): ________________________

1. Complete cardiac diagnosis(es) (include functional classification):

________________________ ____________/____________ (Date of onset) (Date of 1st visit)

________________________ ____________/____________ (Date of onset) (Date of 1st visit)

2. Signs and/or symptoms:

Current Status or Prognosis:

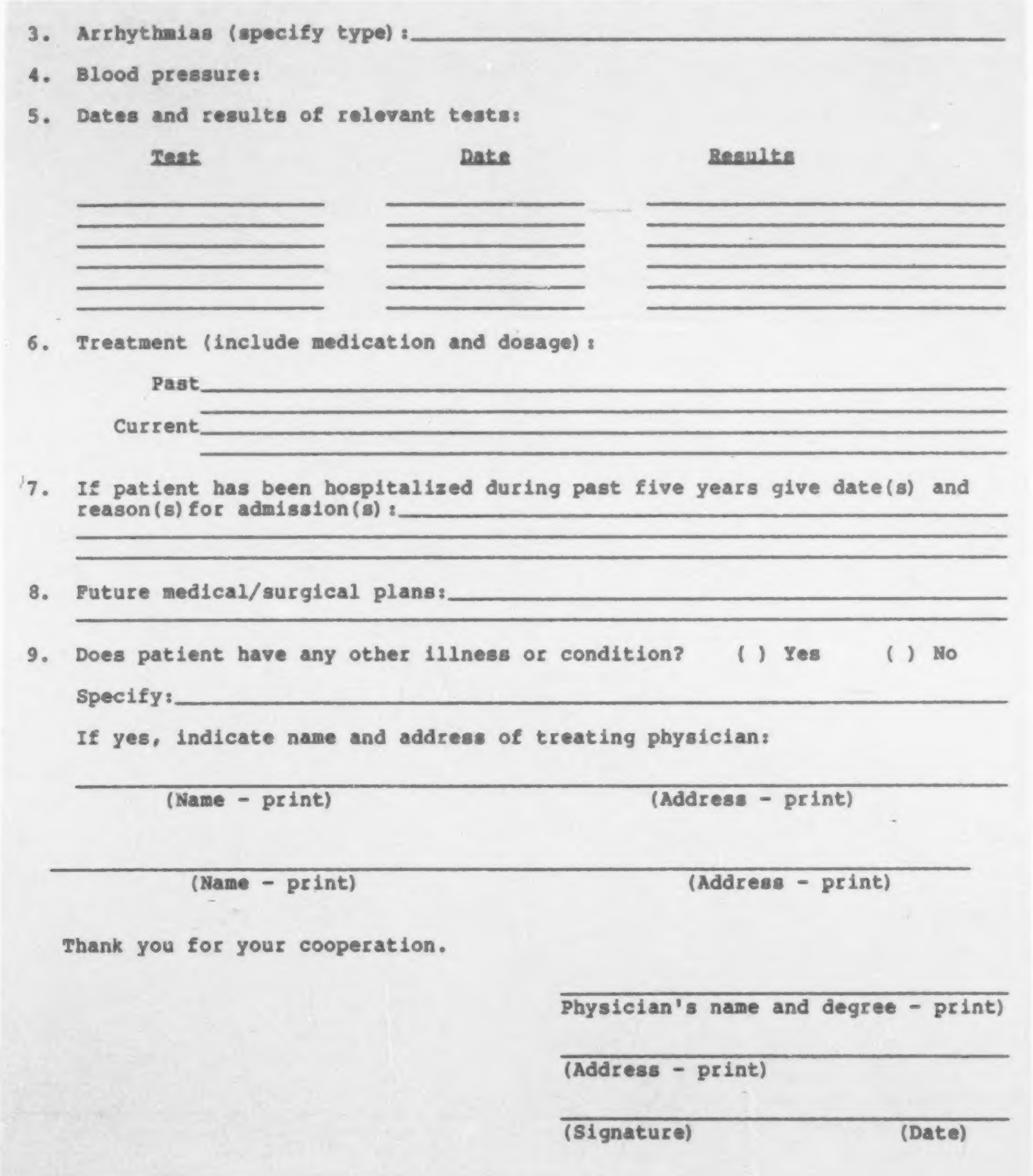
( ) Chest pain
( ) Dyspnea
( ) Orthopnea
( ) Edema
( ) Murmur

( ) Claudication
( ) Palpitations
( ) Syncope
( ) Other________________________
________________________

Details (including duration):________________________
________________________
________________________

HOSPITAL SERVICE PLAN OF
MEDICAL-SURGICAL PLAN OF

Figure 2-5.—Diagnosis-Specific Attending Physician Statement Used by a Blue Cross/Blue Shield Plan—Continued



3. Arrhythmias (specify type): ____________________

4. Blood pressure:

5. Dates and results of relevant tests:

| Test | Date | Results |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

6. Treatment (include medication and dosage):

Past ____________________

Current ____________________

7. If patient has been hospitalized during past five years give date(s) and reason(s) for admission(s): ____________________

8. Future medical/surgical plans: ____________________

9. Does patient have any other illness or condition? ( ) Yes ( ) No

Specify: ____________________

If yes, indicate name and address of treating physician:

____________________
(Name - print) (Address - print)

____________________
(Name - print) (Address - print)

Thank you for your cooperation.

____________________
Physician's name and degree - print)

____________________
(Address - print)

____________________
(Signature) (Date)

Table 2-15.—Underwriting by BC/BS Plans: Health and Other Information Requirements

| Required underwriting information (percent of applicants) | Individual policies (n=15) | | Small group policies (n=14) | | Large group policies[a] (n=15) | |
|---|---|---|---|---|---|---|
| | Number of of plans | Percent of of plans[b] | Number of of plans | Percent of of plans[b] | Number of of plans | Percent of of plans[b] |
| **Attending physician statement (APS):** | | | | | | |
| Never used | 2 | 13% | 6 | 43% | 10 | 67% |
| 1 to 19% | 1 | 7 | 5 | 36 | 4 | 27 |
| 20 to 39% | 8 | 53 | 2 | 14 | 0 | — |
| 40 to 59% | 2 | 13 | 1 | 7 | 1 | 7 |
| 60 to 79% | 2 | 13 | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — | 0 | — |
| Not available | 0 | — | 0 | — | 0 | — |
| Total | 15 | 100% | 14 | 100% | 15 | 100% |
| **Physical exam:** | | | | | | |
| Never used | 13 | 87% | 13 | 93% | 14 | 93% |
| 1 to 19% | 1 | 7 | 1 | 7 | 1 | 7 |
| 20 to 39% | 1 | 7 | 0 | — | 0 | — |
| 40 to 59% | 0 | — | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — | 0 | — |
| Not available | 0 | — | 0 | — | 0 | — |
| Total | 15 | 100% | 14 | 100% | 15 | 100% |
| **Blood or urine screens:** | | | | | | |
| Never Used | 14 | 93% | 13 | 93% | 14 | 93% |
| 1 to 19% | 1 | 7 | 1 | 7 | 1 | 7 |
| 20 to 39% | 0 | — | 0 | — | 0 | — |
| 40 to 59% | 0 | — | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — | 0 | — |
| Not available | 0 | — | 0 | — | 0 | — |
| Total | 15 | 100% | 14 | 100% | 15 | 100% |
| **Financial or personal investigation:** | | | | | | |
| Never used | 14 | 93% | 13 | 93% | 14 | 93% |
| 1 to 19% | 1 | 7 | 1 | 7 | 1 | 7 |
| 20 to 39% | 0 | — | 0 | — | 0 | — |
| 40 to 59% | 0 | — | 0 | — | 0 | — |
| 60 to 79% | 0 | — | 0 | — | 0 | — |
| 80 to 100% | 0 | — | 0 | — | 0 | — |
| Not available | 0 | — | 0 | — | 0 | — |
| Total | 15 | 100% | 14 | 100% | 15 | 100% |

[a] Only late applicants to large groups are required to provide health and related information to obtain coverage.
[b] Percentages may not total to 100 due to rounding.

SOURCE: Office of Technology Assessment, 1988.

applicants for HIV infection. See below for details regarding HIV screening.)

Thus, as for the commercial insurers, the APS appears to be the principal source of testing information for the BC/BS plans.

**Health Maintenance Organizations.**—The principal source of health information for the HMO underwriter is the health history portion of the enrollment application. The survey findings indicate that like BC/BS applicants, the average HMO applicant receives less scrutiny than a commercial insurance applicant. Most HMOs make no inquiries beyond the health history portion of the application and an attending physician statement. It is the rare HMO plan that demands a physical exam, blood chemistry, or urinalysis. None of the respondents reported requiring an APS, physical, or laboratory test for large group applicants.

*Health History Questionnaire.*—All but 1 of the 15 plans reported that individual applicants must

### Table 2-16.—Individual Underwriting by Blue Cross/Blue Shield Plans: Reasons for Requesting an Attending Physician Statement

| Reasons | Number of plans (n = 14)[a] | Percent of plans |
|---|---|---|
| Diagnosis reported on application | 14 | 100% |
| Drug abuse history | 12 | 86 |
| Age | 4 | 29 |
| Late group applicants | 1 | 7 |
| Sex | 1 | 7 |
| Sexual orientation | 0 | — |
| Geographic area | 0 | — |
| Inspection report | 0 | — |
| Other, including: | | |
| Claims history | 5 | 36 |
| Height/weight | 2 | 14 |

[a] One plan did not answer this question.

SOURCE: Office of Technology Assessment, 1988.

complete a medical history questionnaire, and for 5 HMOs (33 percent) it was the sole evidence of the applicant's health.

*Attending Physician Statements.*—At least half of the responding HMOs went beyond the enrollment application and requested an APS for 10 to 85 percent of their nongroup applicants and 10 to 20 percent of small group applicants. All the plans said that the applicant's self-reported medical history could trigger an APS request. In addition, an APS was ordered routinely by five plans (33 percent) in cases of drug abuse history; two plans, because of age, previous prescription drug use, or claims history; and one plan, for late application to a large group (table 2-17).

HMO physician statements do not differ from those used by commercial insurers or BC/BS plans; physicians are asked to describe the applicant's recent health history and provide laboratory findings.

*Physical Exams.*—Only 3 of the 15 respondents accepting individuals reported requiring a physical exam as a condition of enrollment for 2 to 30 percent of self-pay applicants. One of these plans required 30 percent of its applicants to get a physical at their own expense. No plan reported requiring physicals for small group applicants. Medical history, APS findings, and age were reported

### Table 2-17.—HMOs: Health and Other Information Requirements

| Required underwriting information (percent of applicants)[a] | Individual applicants (n = 15) | | Small group applicants (n = 8) | |
|---|---|---|---|---|
| | Number | Percent[b] | Number | Percent |
| **Attending physician statement (APS):** | | | | |
| Never used | 5 | 33% | 4 | 50% |
| 1 to 19% | 2 | 13 | 3 | 38 |
| 20 to 39% | 1 | 7 | 1 | 12 |
| 40 to 59% | 1 | 7 | 0 | — |
| 60 to 79% | 2 | 13 | 0 | — |
| 80 to 100% | 2 | 13 | 0 | — |
| Not available | 2 | 13 | 0 | — |
| Total | 15 | 100% | 8 | 100% |
| **Physical exam:** | | | | |
| Never used | 10 | 67% | 7 | 88% |
| 1 to 19% | 1 | 7 | 0 | — |
| 20 to 39% | 2 | 13 | 0 | — |
| Not available | 2 | 13 | 1 | 12 |
| Total | 15 | 100% | 8 | 100% |
| **Blood or urine screens:** | | | | |
| Never used | 12 | 80% | 7 | 88% |
| 1 to 19% | 1 | 7 | 0 | — |
| 20 to 39% | 1 | 7 | 0 | — |
| 80 to 100% | 1 | 7 | 0 | — |
| Not available | 0 | — | 1 | 12 |
| Total | 15 | 100% | 8 | 100% |

[a] Intervals with no reported frequency are omitted.
[b] Percentages may not total 100 due to rounding.

SOURCE: Office of Technology Assessment, 1988.

as reasons for requiring a physical. In addition, one plan noted an unofficial policy requiring routine examinations of applicants thought to be homosexual (e.g., single men 35 years or older).

*Blood and Urine Screening.*—HMO screening is as uncommon as physical exams; only three plans reported sometimes testing individual applicants. One plan required a complete blood count and urine check for 20 percent of its individual applicants. Another ordered a complete blood count, cholesterol check, and urinalysis for 85 percent of their self-pay applicants. The third plan reported testing very infrequently (i.e., less than 1 percent) and always in conjunction with a physical exam. No plan reported requiring blood or urine screens for small group applicants.

Thus, the APS also is the principal source of testing data for HMOs.

### AIDS Policies and Experience

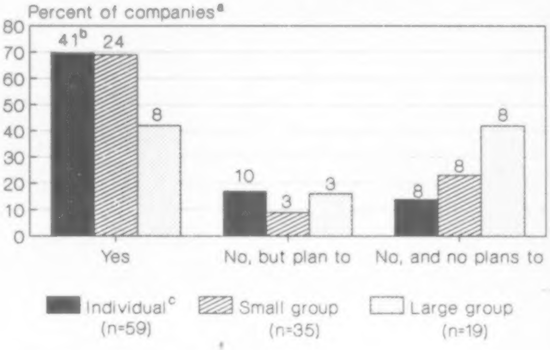
**Commercial Insurers.**—The survey asked several questions concerning AIDS underwriting policies and claims experience:

*Do Health Insurers Attempt to Identify Applicants Exposed to the AIDS Virus?*—Fifty-one (86 percent) responding commercial insurers either screen or plan to screen individual health insurance applicants for infections with the AIDS virus through some method; of these companies, 41 do it currently and 10 plan to do so (figure 2-6).

Efforts to identify high-risk group applicants are also common. Twenty-seven small group (77 percent) and 11 large group insurers (58 percent) either screen or plan to screen through some method (figure 2-6).

*How Do Insurers Screen for AIDS Exposure?*—Not every company interested in identifying a proposed insured's HIV status, or risk for AIDS, tests applicants. Many rely on the application's health history questionnaire and attending physician statements to evaluate the risk for AIDS. Medical Information Bureau reports also play an important role and may serve as a catalyst for testing an applicant or scrutinizing more carefully an applicant's health history (figure 2-7).[34]

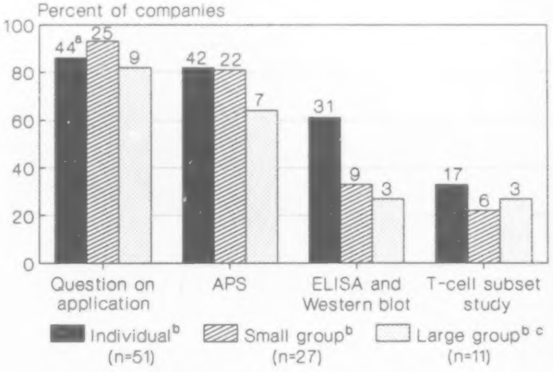
**Figure 2-6.-Commercial Health Insurers Attempting To Identify Applicants Exposed to the AIDS Virus**



[a]Percentages may not total 100 due to rounding.
[b]Represents the number of responding companies.
[c]Data were unavailable for two individual, three small group, and eight large group insurers.

SOURCE: Office of Technology Assessment, 1988.

**Figure 2-7.-Commercial Health Insurers: Methods Used To Identify AIDS Exposure**



[a]Represents the number of responding companies.
[b]Only those respondents screening or intending to screen for AIDS exposure are included. Data were unavailable for one small and one large group insurer.
[c]Only "late applicants" to large groups are screened.

SOURCE: Office of Technology Assessment, 1988.

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[34] On May 14, 1987, the MIB announced that, in response to confidentiality concerns expressed by gay rights advocates, it "will no longer keep records that show an applicant for insurance has tested positive for the AIDS virus antibodies" (2). MIB reports now use a more general code that indicates an "abnormal" blood count (without identifying the test) while continuing to report other high-risk indicators including symptoms of AIDS, history of sexually transmitted disease, drug abuse, etc.

The most common approach to screening potential insureds for AIDS is by incorporating a question in the health history portion of the application. All but seven of the companies (86 percent) who screen individual applicants use an AIDS question. Ninety-three percent (25 of 27) of small group insurers and 82 percent (9 of 11) of large group insurers who screen also use this method.

It is important to realize that including an AIDS question on the application is not only an effective screen but also a tool for contesting preexisting condition claims. If an applicant knowingly misrepresents his or her health condition (e.g., recognized symptoms of AIDS, or fully diagnosed AIDS or ARC), the insurer may have grounds for subsequently denying reimbursement for the condition or rescinding coverage altogether. (See discussion below concerning insurers' reported experience with preexisting condition claims for AIDS.)

AIDS-directed questions vary; some ask about test results, others detail symptoms or inquire whether the applicant has been diagnosed or treated for AIDS or an AIDS-related condition. An admission of AIDS, ARC, or HIV seropositivity results in immediate refusal of the application. The survey did not clarify whether applicants with a history of sexually transmitted disease or AIDS symptoms are also automatically rejected. These are some typical examples of questions appearing in policy applications:

- Ever had Acquired Immune Deficiency Syndrome (AIDS), "AIDS" Related Complex (ARC), or tested positive for antibodies to the "AIDS" HTLV-III Virus?
- Social or venereal disease of any type?
- Recurrent fever, fatigue, or night sweats?
- Had a fever of more than three weeks' duration, weight loss of more than 15 pounds in two months, diarrhea of more than one month's duration, persistent skin rash or oral lesions (infections or sores of the mouth)?
- During the past ten years, has any person to be insured consulted a physician or practitioner for, been treated for, had, or been informed that he or she had, Acquired Immune Deficiency Syndrome (AIDS), AIDS Related Complex (ARC), or other immune deficiency?

Underwriters frequently order an APS to help evaluate an applicant's risk for AIDS; 82 percent or more of those screening individuals (42 of 51) for AIDS exposure require applicants' physicians to submit an APS describing their recent health history and laboratory and other diagnostic test results (figure 2-7). Eighty-one percent of small group (22 of 27) and 64 percent (7 of 11) of large group insurers also order an APS. In addition to possibly revealing AIDS symptoms or other risk factors, the APS may report the applicant's HIV status. If a photocopied medical record is submitted in lieu of the standard APS (a common practice among physicians), the applicant's sexual preference may be indicated as well.

HIV testing is also quite common. This is particularly true for individual health insurance, where 61 percent of those insurers that screen (and more than half of all respondents) require applicants to pass the ELISA-ELISA-Western blot series. One-third of those that screen individuals (17 of 51) also use the T-cell subset test, presumably in States where HIV testing is prohibited. No company reported using the ELISA test without Western blot confirmation.

Substitution of the T-cell test can be problematic even for the healthy insurance applicant. In California, where HIV testing is prohibited and T-cell testing is common, the Department of Insurance has received complaints from *HIV-negative* individuals who were unable to obtain insurance because of positive T-cell test findings (115).

HIV testing is less common among the responding group insurers; only nine of the small group (33 percent) and three of the large group insurers (27 percent) require an ELISA and Western blot for some applicants. T-cell subset studies are also ordered in States where HIV testing is prohibited by six small group (22 percent) and 3 large group insurers (27 percent).

No insurer reported using any blood test alternative other than the T-cell subset study.

*Who Is Required To Have an AIDS Test?*—Thirty-one (51 percent) of the respondents routinely tested individual health insurance applicants for HIV antibodies; of these, 7 test all applicants, 14 test only those considered to be "high-risk," and 10 test according to various criteria (e.g., State of residence, medical history, policy amount, etc.). Nine small group insurers routinely HIV-test; one tests all applicants, five test "high-risk" applicants, and three test according to other criteria. Three large group insurers test only those applicants thought to be at risk (table 2-18).

"High-risk" is defined differently by each company; history of sexually transmitted disease was the most commonly reported criteria, although those with a history of drug abuse, receiving blood transfusions, and hemophiliacs are also frequently tested. Many companies, however, reported that hemophiliacs and known drug abusers are automatically denied coverage. Three companies noted that for residents in areas of high AIDS prevalence, particularly New York and California, 100 percent of their applicants are HIV-tested. Applicants in California, where HIV antibody testing is prohibited, undergo the T-cell test (table 2-18).

*How Many Individuals Have Insurers Reimbursed for AIDS-Related Claims?*—Almost three-quarters of the individual insurers (45 of 61) responding to the survey had reimbursed at least one policyholder (or dependent) for AIDS-related care. In total, 1,010 AIDS cases were reported and, on average, each insurer financed the care of 22 AIDS-related cases. The range of the AIDS "burden" on each insurer, however, varied widely. For individual health insurance, for example, payments for AIDS-related services ranged from no cases (6 companies) up to 269 (1 company). More than half of the companies (34 of 61) reported 10 reimbursable AIDS cases or fewer, while only 4 have reimbursed 50 or more individuals for AIDS-related care (figure 2-8).

Of the 20 insurers providing AIDS case data for their small group policies, 6 reported no AIDS-related cases and 14 had from 1 to 50, totalling 146. Twenty-two large group insurers reported

**Table 2-18.—Commercial Health Insurers: HIV Testing Practices and Criteria for High-Risk Individual, Small Group, and Large Group Applicants**

| | Individual applicants (n=61) | Small group applicants (n=38) | Large group applicants[a] (n=27) |
|---|---|---|---|
| Surveyed companies requiring HIV test | 31 (51%) | 9 | 3 |
| Who do they test?[b] | | | |
| All applicants | 7 | 1 | 0 |
| High-risk applicants only | 14 | 5 | 2 |
| Other, including: | 7 | 3 | 1 |
| High incidence areas-all; elsewhere based on medical history | 2 | 1 | 0 |
| New York and California-all; elswhere based on medical history | 1 | 0 | 0 |
| Anyone whose blood is drawn | 1 | 0 | 0 |
| Policy amounts more than $100,000 | 1 | 0 | 0 |
| If medical history warrants it | 2 | 1 | 1 |
| Criteria care under review | 0 | 1 | 0 |
| Who is considered high-risk? | | | |
| All males | 1 | 1 | 0 |
| History of sexually transmitted disease | 15 | 7 | 3 |
| Hemophiliacs[c] | 7 | 5 | 3 |
| History of receiving blood transfusions | 8 | 5 | 3 |
| Drug abusers[c] | 10 | 6 | 3 |
| Other, including: | | | |
| AIDS symptoms present | 4 | 0 | 0 |
| History of hepatitis | 1 | 0 | 0 |
| Individual consideration | 1 | 0 | 0 |
| Medical history | 1 | 1 | 1 |

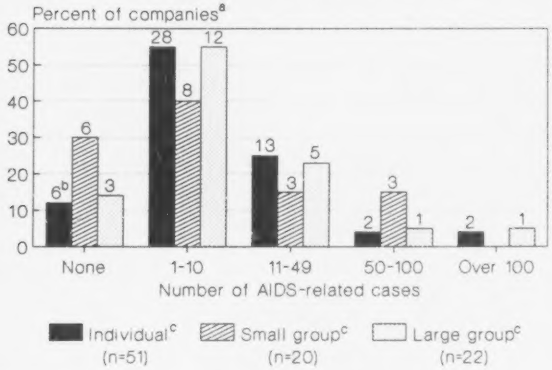
[a] Only "late applicants' to large groups are tested.

[b] Three of the thirty-one individual insurers that HIV test did not answer this question.

[c] Numerous carriers noted that they do not underwrite hemophiliacs or drug abusers under any conditions.

SOURCE: Office of Technology Assessment, 1988.

**Figure 2-8.-Commercial Health Insurers: Number of AIDS-Related Cases**



[a] Percentages may not total 100 due to rounding.
[b] Represents the number of responding companies.
[c] Data were unavailable for 10 individual, 18 small group, and 27 large group insurers.

SOURCE: Office of Technology Assessment, 1988.

613 AIDS-related cases; 3 had no cases, 12 had 1 to 10, and 6 had 11 to 100, and 1 company alone, 350.

It is important to note here that surveillance of AIDS-related cases and of costs to insurers is sketchy at best. Sixteen percent (10 of 61) of the individual and 47 percent (18 of 38) of the small group health insurers noted that case data were unknown or unavailable, and the majority of those responding reported collecting AIDS-related case data only since 1986. Cost projections for AIDS cases were not provided by two-thirds of the individual and 82 percent of the small group insurers. Many commented to OTA that identifying AIDS-related cases is often difficult and, if data collection systems do exist, cases and costs are probably undercounted. Moreover, it is not standard practice among most insurers to project annual costs or claims by diagnosis.

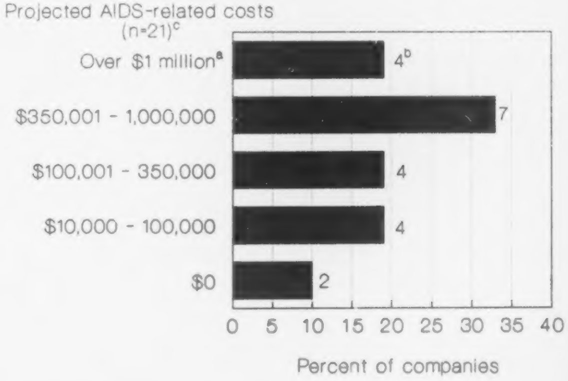
Poor reporting of AIDS-related data may be, in part, a reflection of the minimal impact of the disease in many locales around the country. An official of 1 of the 5 largest individual health insurers, despite reporting 269 AIDS-related cases and historical costs of more than $3.2 million, commented to OTA that AIDS "is just a drop in the bucket."

*What Costs Do Insurers Project for AIDS-Related Claims for 1987?*—Twenty-one companies provided projections of AIDS-related claims costs for 1987, forecasting total claims of $11.04 million for individual health policies, an average of $0.53 million per individual insurer. Projections ranged tremendously; two companies did not expect any AIDS cases this year (both specialize in insurance for seniors), while four projected costs of $1.3 to $2.3 million for individual health policies (figure 2-9). (As noted above, one carrier reported more than $3.2 million in AIDS-related claims to date.)

Seven small group insurers forecast a total of $1.5 million AIDS-related costs for 1987, ranging from none at one firm up to $618,000 at another. Seven large group insurers projected a total $488,600; an additional company reported that it expected 1987 AIDS-related group claims to total $5 to $10 million.

*What Proportion of Insureds With AIDS Have Been Found To Have a Preexisting Condition for AIDS?*—Preexisting condition clauses are used universally by health insurers and significantly restrict reimbursement for medical conditions that existed before the effective date of coverage. Two

**Figure 2-9.-Commercial Health Insurers: Range of 1987 AIDS-Related Cost Projections for Individual Subscribers**



[a] One respondent was unable to project 1987 costs but reported historical costs of $3.22 million for 269 individual subscribers.
[b] Represents the number of responding companies.
[c] Forty individual insurers (almost two-thirds of the respondents) were unable to provide AIDS-related cost data.

SOURCE: Office of Technology Assessment, 1988.

key time periods set limits on the insurer's financial responsibility for such conditions: the length of time before and the length of time after the policy goes into effect. The NAIC has issued several relevant model regulations. Regulations to implement their Individual Accident and Sickness Insurance Minimum Standards Act define a preexisting condition as ". . . the existence of symptoms which would cause an ordinarily prudent person to seek diagnosis, care or treatment" or "a condition for which medical advice or treatment was recommended by a physician or received from a physician within a *5-year period preceding the effective date of the coverage* of the insured person" (emphasis added) (213).[35] In addition, no claim for losses incurred after a *2-year waiting period starting on the policy date* should be denied on the ground that the disease or physical condition was preexisting (213).

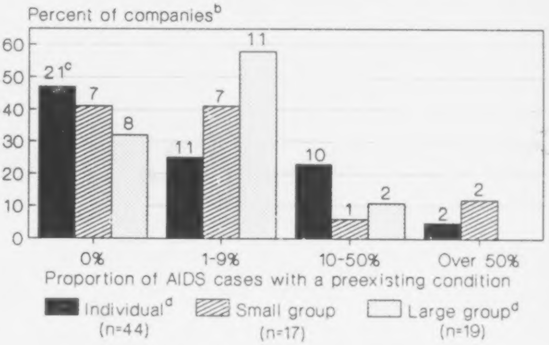
Though most experts agree that HIV seropositivity does not meet the NAIC definition of a preexisting condition, the head underwriter of a top-10 company told OTA of denying reimbursement on that basis. At present, there are several court cases pending relating to what comprises a preexisting condition for AIDS and the alleged refusal by insurer(s) to pay for AIDS-related claims based on a policy's preexisting condition provision.

Almost half (21 of 44) of the individual health insurers who had received at least one AIDS-related claim reported finding no preexisting AIDS-related cases. Eleven found 1 to 9 percent of cases to be preexisting; 10 companies discovered 10 to 50 percent. Two companies reported more than 50 percent (figure 2-10).

Seven small group insurers found no AIDS-related claims to be linked with a preexisting condition; another seven reported 1 to 9 percent; one reported 10 to 50 percent; and two, more than 50 percent.

Six of the large group insurers reporting AIDS-related claims identified none as preexisting, 11 found 1 to 9 percent, and 2 found 10 to 50 percent.

**Figure 2-10.—Commercial Health Insurers: Percent of AIDS Cases Determined To Be Preexisting[a]**



[a] Only those respondents providing AIDS case data are included.
[b] Percentages may not total 100 due to rounding.
[c] Represents the number of responding companies.
[d] Data were unavailable for one individual and 22 large group insurers reporting AIDS cases.

SOURCE: Office of Technology Assessment, 1988.

*What Plans Have Companies Made in Response to the Financial Impact of AIDS?*—Beyond the actions already taken by many insurers, and reported above, many companies have additional plans in the works. The most common are plans to reduce company exposure in the individual and small group health insurance markets (e.g., by introducing tighter underwriting guidelines) and to expand HIV or other testing. One-third of those responding (20 of 61) plan one or both of these measures. Nine companies intend to add an AIDS question to the health history portion of their application forms. Five reported plans to exclude AIDS and/or sexually transmitted diseases from individual health coverage. Other planned measures include placing a dollar limit on AIDS coverage in new policies and establishing a waiting period for AIDS benefits (table 2-19).

No insurer cited plans to withdraw from the individual health market; however, one of the largest surveyed insurers noted its withdrawal from the Washington, DC, area. (The District of Columbia has the nation's most stringent prohibitions regarding AIDS testing and underwriting.) Nonetheless, it is difficult to assess whether AIDS has reduced the availability of nongroup health coverage; insurers, for example, can effectively

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[35] As of October 1987, the regulation had been adopted by 20 States (16).

Table 2-19.—Response to the AIDS Epidemic: Reported Plans by Commercial Health Insurers, BC/BS Plans, and HMOs

| | Commercial insurers (n=61) | | BC/BS plans (n=15) | | HMOs (n=16) | |
|---|---|---|---|---|---|---|
| Reported plans | Number | Percent | Number | Percent | Number | Percent |
| Withdraw from the individual health market altogether[a] | 0 | — | 0 | — | 1 | 6% |
| Exclude AIDS and/or sexually transmitted diseases from individual health coverage | 5 | 8% | 1 | 7% | 0 | — |
| Reduce company exposure in the individual and small group health markets (e.g., by introducing more restrictive underwriting guidelines) | 21 | 34 | 6 | 40 | 5 | 31 |
| Expand HIV or other testing of applicants | 20 | 33 | 1 | 7 | 2 | 13 |
| Terminate open enrollment | NA[b] | — | 0 | — | 0 | — |
| Other: | | | | | | |
| Considering one or more of the above | 3 | 5 | 0 | — | 0 | — |
| Would consider any of the above policies if they were adopted by competing HMOs | NA | — | NA | — | 1 | 6 |
| Add an AIDS question to application | 9 | 15 | 2 | 13 | 0 | — |
| Include a dollar limit for AIDS care in new policies | 2 | 3 | 0 | — | 0 | — |
| Establish a 12-24 month waiting period for AIDS | 1 | 2 | 0 | — | 0 | — |
| Deny applicants with a history of sexually transmitted disease and expand waiting period for hepatitis, lymph disease, and mononucleosis | 0 | — | 1 | 7 | 0 | — |
| Expand education role | 0 | — | 2 | 7 | 0 | — |
| Policies currently under review | 0 | — | 2 | 13 | 2 | 13 |
| Considering HIV testing | 0 | — | 0 | — | 1 | 6 |
| No actions planned or reported | 10 | 16 | 2 | 13 | 7 | 44 |

[a] One commercial insurer reported withdrawing from the Washington, D.C. market.
[b] NA = Not applicable.

SOURCE: Office of Technology Assessment, 1988.

eliminate their role in the market by pricing nongroup policies so high that no one will buy them (218).

**Blue Cross/Blue Shield Plans.**—The survey asked several questions concerning AIDS underwriting policies and claims experience:

*Do Blue Cross/Blue Shield Plans Attempt To Identify Applicants Exposed to the AIDS Virus?*—Eleven or 73 percent of the respondents either screen or plan to screen nongroup applicants for AIDS exposure by one method or another; of these, eight currently screen nongroup applicants and three plan to. One additional plan noted that its AIDS policies are under review (figure 2-11).

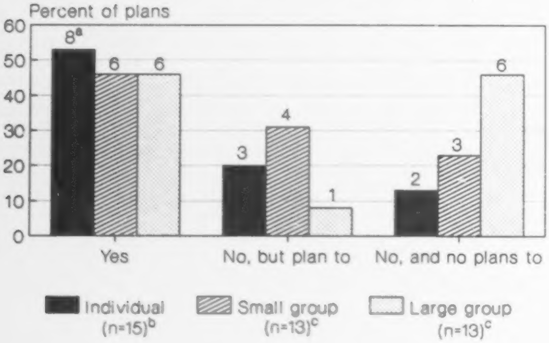
BC/BS efforts to identify high-risk group applicants are also common. Ten small group (77 percent) and 7 large group plans (54 percent) either screen or plan to screen through some method (figure 2-11).

*How Do Blue Cross/Blue Shield Plans Screen for AIDS Exposure?*—The plans' approach to screening for AIDS very much mirrors their general approach to underwriting. The health history questionnaire along with an attending physician statement are the principal means for assessing an applicant's health. Testing is very rare (figure 2-12).

All the plans that try to identify applicants exposed to the AIDS virus use an AIDS-related question in applications for nongroup, small group, and large group coverage. The BC/BS approach to asking about AIDS differs from many commercial carriers. Rather than ask about AIDS-related symptoms or test results, the plans have simply added AIDS and/or ARC to their health history diagnoses lists. Venereal disease is also included by five plans. One plan asks a more general question concerning "positive test results for immune disorders" because it is prohibited, by State regulations, from asking directly about AIDS. Interestingly, a continuous, open enrollment plan that does not screen for AIDS exposure specifically instructs the applicant not to indicate need for medical advice or treatment "because you have had a positive result on an AIDS test—HTLV-III."

An admission of AIDS, ARC, or HIV seropositivity results in immediate refusal of the application except in open enrollment plans. As in the case of commercial insurers, BC/BS plans include an AIDS question on the application not only for screening purposes but also as a tool for contesting preexisting condition claims. If an applicant knowingly misrepresents his or her health condition, the plan may have grounds for denying reimbursement for the condition or rescinding coverage altogether. (See discussion below concerning BC/BS reported experience with preexisting condition claims for AIDS.)

Figure 2-11.-BC/BS Plans Attempting To Identify Applicants Exposed to AIDS



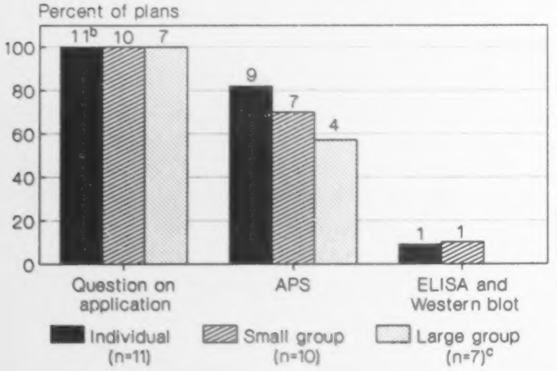
[a] Represents the number of responding companies.

[b] Not shown above are one plan that was reviewing its AIDS policies and another plan that attempts to identify AIDS exposure for less than 0.5% of individual applicants.

[c] Data were unavailable for one small group and two large group plans.

SOURCE: Office of Technology Assessment, 1988.

Figure 2-12.-BC/BS Plans: Methods Used To Identify AIDS Exposure[a]



[a] Only those respondents screening or intending to screen for AIDS exposure are included.

[b] Represents the number of responding companies.

[c] Only "late applicants" to large groups are screened.

SOURCE: Office of Technology Assessment, 1988.

Nine plans (82 percent) may ask for an APS to help evaluate a nongroup applicant's risk for AIDS. Seventy percent of small group (7 of 10) and 54 percent (7 of 11) of large group plans (4 of 7) also order an APS for some applicants. The APS may indicate AIDS symptoms, other risk factors, HIV status, and even sexual preference.

Only one plan intends to test some applicants for HIV infection (using the ELISA-ELISA-Western blot series). No plan reported using the T-cell subset test.

*Who Is Required To Have an AIDS Test?*—As noted above, only one plan expects to test some nongroup and small group applicants for HIV infection. Anyone considered to be "high-risk" will be required to undergo the ELISA-ELISA-Western blot series. The plan's criteria for "high-risk" include: 1) all males, 2) history of sexually transmitted disease, 3) hemophiliacs, 4) history of receiving blood transfusions, and 5) drug abusers.

*How Many Blue Cross/Blue Shield Subscribers Have Been Reimbursed for AIDS-Related Claims?*—BC/BS surveillance of AIDS-related cases and costs seems sketchy at best. One-third of the plans noted that case data were unknown or unavailable, and the majority reported collecting AIDS-related data only since summer 1985. Several plans indicated that they are just now developing systems for better identifying subscribers diagnosed with AIDS-related illnesses; furthermore, current caseload data are probably underestimated. Ten of the fifteen respondents were not able to provide projections of AIDS-related claims costs for 1987 (table 2-20). Most of the plans that provided relevant data were unable to identify AIDS-related cases or costs by type of coverage (i.e., individual vs. group). Consequently, aggregate data is presented here reflecting both individual and group policy experience.

Table 2-20.—Blue Cross/Blue Shield Plans: Number of Subscribers Reimbursed for AIDS-Related Claims

| | No open enrollment (n=10) | Open enrollment (n=5)[a] | All plans (n=15) |
|---|---|---|---|
| Total number of subscribers reimbursed for AIDS-related claims[b] | 453 | 3,480 | 3,933[c] |
| Number of plans reporting AIDS-related claims | 7 (70%) | 3 (60%) | 10 (67%) |
| Average number of AIDS-related cases per plan | 65 | 1,160 | 393 |

[a] One of the five plans holds a limited open enrollment period; the others are continuous.

[b] AIDS-related claims data reflect both individual and group policy experience.

[c] One plan alone reported 3,000 subscribers with AIDS; the other plans had an average AIDS-related caseload of 104.

SOURCE: Office of Technology Assessment, 1988.

Ten plans reported reimbursing 3,933 subscribers for AIDS-related care, an average of 393 subscribers per plan. The range in caseload was tremendous, from only 1 to 3,000 subscribers. Along with the obvious effect of location on regionally based insurers such as BC/BS plans, market share and open enrollment seem to critically determine a plan's AIDS "burden."

Open enrollment plans with a large share of the health insurance market appear to be particularly vulnerable if also located in a State that is seriously burdened by the epidemic. The seven plans that never hold an open enrollment period reported a total of 453 AIDS-related cases, an average of 65 subscribers per plan. Three of these plans are located in areas of high AIDS prevalence, and only one has historically held a significant market share (i.e., close to 40 percent) (84). In stark contrast, the three plans that are continuously open reported reimbursing 3,480 subscribers for AIDS-related care, an average of 1,160 cases per plan. Two of these plans are in areas of high AIDS prevalence, one plan alone accounts for 3,000 cases. All three have historically held large market shares ranging from 60 to 75 percent (table 2-20).

*What Costs Do the BC/BS Plans Project for AIDS-Related Claims for 1987?*—Only five plans provided 1987 claims projections. Three non-open enrollment plans forecast a total of $29.6 million in AIDS-related claims for 1987 ($20 million was for one plan alone). Two of these plans are located in high-risk regions. Claims totaling $27 million were projected by two open enrollment plans, $23 million for one plan and and $4 million for the other (table 2-21).

*What Proportion of Subscribers With AIDS Were Found To Have a Preexisting Condition for AIDS?*—Six of the 10 plans that have identified at least one subscriber with AIDS reported finding that 1 to more than 50 percent of these subscribers had a preexisting condition for AIDS. Two of these plans, both in areas of high AIDS prevalence, linked more than half of their AIDS cases with a preexisting condition (table 2-22). This may be evidence of adverse selection and the effort of AIDS sufferers to obtain insurance protection after an AIDS-related diagnosis had been made or seriously suspected.

*What Plans Have BC/BS Plans Made in Response to the Financial Impact of AIDS?*—All but two of the respondents report some action in response to the AIDS epidemic. Six plans (40 percent) noted intentions to reduce their exposure in the individual and small group health markets. One cited intentions to expand HIV or other testing of applicants while also excluding AIDS and/or sexually transmitted diseases from individual health coverage. Others reported intentions to add an AIDS question to enrollment applications, deny applicants with a history of sexually transmitted disease, and lengthen the waiting period for new subscribers with a history of hepatitis, lymph disease, and mononucleosis. Two plans (one holds continuous open enrollment) intended to expand their AIDS education efforts, and two others are currently reviewing their AIDS-related policies (table 2-19).

**Health Maintenance Organizations.**—The survey asked several questions concerning AIDS underwriting policies and claims experience:

**Table 2-21.—Blue Cross/Blue Shield Plans: Projected AIDS-Related Claims Cost for 1987**

| | No open enrollment (n=10) | Open enrollment (n=5)[a] | All plans (n=15) |
|---|---|---|---|
| Total projected AIDS-related claims cost for 1987[b] | $29.6 million | $27.0 million | $56.6 million |
| Number of companies reporting projections | 3 (30%) | 2 (40%) | 5 (33%) |
| Average projected cost for 1987 | $9.9 million | $13.5 million | $11.3 million |
| Range | $2.6 to $20 million | $4 to $23 million | $2.6 to $23 million |

[a] One of the five plans holds a limited open enrollment period; the others are continuous.

[b] AIDS-related cost projections include individual and group policies.

SOURCE: Office of Technology Assessment, 1988.

**Table 2-22.—BC/BS Plans Reporting AIDS Cases: Prevalance of Cases With Preexisting Condition for AIDS**

| | Individual and group policies | |
|---|---|---|
| Proportion of AIDS cases with a preexisting condition for AIDS[a] | Number of plans (n=9) | Percent of plans |
| 0 percent | 3[b] | 30% |
| 1 to 9 percent | 2 | 20 |
| 10 to 50 percent | 2[c] | 20 |
| Greater than 50 percent | 2 | 20 |

[a] Only those nine plans that reported AIDS-related cases and preexisting condition data are included. A tenth plan reported 230 cases but the related preexisting condition data were unavailable.

[b] One of these plans reported that while no small or large group cases were preexisting, 1 to 9 percent of its individual AIDS-related cases were linked with a preexisting condition.

[c] One of these plans reported that while 10 to 50 percent of its small and group cases were preexisting, more than half of its individual AIDS-related cases were linked with a preexisting condition.

SOURCE: Office of Technology Assessment, 1988.

*Does the HMO Attempt To Identify Applicants Exposed to the AIDS Virus?*—Half or more of the respondents screen or plan to screen individual (8 of 15) and small group applicants (4 of 8) for exposure to the AIDS virus by one method or another. Three of the plans that do not try to identify individual applicants exposed to AIDS are prohibited from doing any medical screening by State law. One plan noted that it is currently formulating its AIDS policies (table 2-23).

*How Does the HMO Screen for AIDS Exposure?*—The responding HMOs rely primarily on the enrollment application and the attending physician statement to identify applicants exposed to the AIDS virus. HIV testing is done by only two plans and is being considered by a third (table 2-24).

Each of the eight plans that screen for HIV infection ask an AIDS-directed question in the health history portion of their enrollment form. Some of the respondents have simply added AIDS and/or ARC to the application's health history list of diagnoses, while one plan asks: "Had any blood tests including any screening for the presence of viral antibodies?"

An admission of AIDS, ARC, or HIV seropositivity results in immediate declination of the application. Like the commercial insurers and BC/BS plans, the HMOs include an AIDS question on the application not only for screening purposes but also as a tool for contesting preexisting conditions. If an applicant knowingly misrepresents his or her health condition, the plan may have grounds for terminating HMO membership.

Six plans (75 percent) reported that they request an APS to help determine an individual applicant's risk for AIDS; two (50 percent) similarly screen small group applicants. As noted earlier, the APS may report AIDS symptoms, other risk factors, HIV status, and even sexual preference.

Only two plans (25 percent) require individual applicants to be tested. Both use the ELISA-ELISA-

**Table 2-23.—HMOs Attempting To Identify Individual and Small Group Applicants Exposed to the AIDS Virus**

| Attempt to identify applicants exposed to the AIDS virus | Individual applicants | | Small group applicants[a] | |
|---|---|---|---|---|
| | Number of HMOs (n=1) | Percent of HMOs | Number of HMOs (n=7) | Percent of HMOs |
| Yes | 8 | 53% | 4 | 57% |
| No, but plans to | 0 | — | 0 | — |
| No, and no plans | 6 | 40 | 2 | 29 |
| Other, including: | | | | |
| —AIDS policies under review | 1 | 7 | 1 | 14 |

[a] One HMO that accepts small group applicants did not answer this question.

SOURCE: Office of Technology Assessment, 1988.

**Table 2-24.—HMOs: Methods Used To Screen Individual and Small Group Applicants for Exposure to the AIDS Virus**

| Method(s) used to identify AIDS exposure[a] | Individual applicants | | Small group applicants[b] | |
|---|---|---|---|---|
| | Number of HMOs (n=8) | Percent of HMOs | Number of HMOs (n=8) | Percent of HMOs |
| Question on application | 8 | 100% | 4 | 50% |
| Attending physician statement | 6 | 75 | 2 | 25 |
| ELISA and Western blot | 2 | 25 | 0 | — |
| T-Cell subset study | 0 | 0 | 0 | — |
| Other, including: | | | | |
| physical exam if high risk | 1 | 13 | 0 | — |

[a] Data include only those HMOs that screen or intend to screen for AIDS.
[b] Two HMOs that screen for AIDS among small group applicants did not report their methods.

SOURCE: Office of Technology Assessment, 1988.

Western blot series. Another plan reported that it is considering plans to introduce HIV testing of applicants. No plan reported testing group applicants or using the T-cell subset test (table 2-24). One plan that is located in a State where HIV testing is prohibited requests a physical exam of all high-risk applicants.

*Who Is Required To Have an AIDS Test?*—As noted above, only two HMOs reported that they test some self-pay applicants for HIV infection. At both plans, anyone considered to be "high-risk" will be required to undergo ELISA-ELISA-Western blot testing. At one plan "high-risk" is defined as a history of sexually transmitted disease or drug abuse. (This plan requires applicants to be tested at their own expense.) The other plan requires test results for HIV exposure for individual/family applicants with any one of twelve conditions, including: acute onset of severe seborrheic dermatitis, history of three or more episodes of any sexually transmitted disease, or Kaposi's sarcoma (figure 2-13).

*How Many Members With AIDS/ARC Have the HMOs had?*—The responding HMOs' AIDS/ARC case data seem to be just as sketchy as the statistics provided by the commercial and BC/BS plans. One HMO identified AIDS cases as early as 1981, some plans reported patients in 1983, while others cited cases as of only this year. As for the BC/BS plans, the HMOs were unable to identify AIDS-related cases or costs by type of coverage (i.e., individual vs. group). Consequently, aggregate data is presented here reflecting both individual and group membership experience. In total, twelve plans reported caring for 1,468 members with AIDS or ARC, an average of 122 members per HMO. The range in cases varied from none at two HMOs to 940 patients at one HMO (figure 2-14).

*What Costs Do the HMOs Project for AIDS-Related Care in 1987?*—Only two HMOs provided projections of AIDS-related costs for 1987. One plan that had identified 10 cases during the first 10 months of 1987 forecast total costs of

**Figure 2-13.—One HMO's Guidelines for Health Evaluation: AIDS and Exposure to the AIDS Virus**

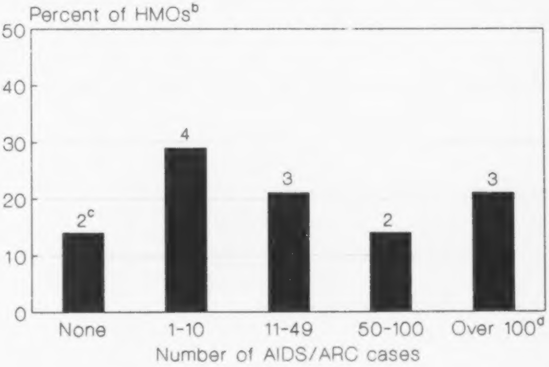
These guidelines define circumstances under which __________________ will require submission of test results for HIV (AIDS virus) exposure prior to consideration of an application for the Individual/Family Plan. These have been developed using criteria suggested by the AIDS Task Force, the Legal Department, and the Eligibility Committee at __________________.

Submission of recent test results (performed 12 months ago or less) for HIV exposure shall be required (using "Western Blot" or other test of equal or greater accuracy) under the following circumstances:

1. Acute onset of severe seborrheic dermatitis in an adult.
2. Generalized adenopathy or unexplained adenopathy.
3. History of illicit IV drug usage which occurred after 1978.
4. Weight loss of more than 10 pounds in the prior 2 years, which is not clearly related to dieting, increased activity, or an acute medical problem.
5. History of 3 or more episodes of any sexually transmitted disease (e.g. chlamydial infections of the sexual organs, gonorrhea, syphilis, condyloma) or 2 episodes of such diseases and an occurance of Hepatitis B which have occurred after 1978.
6. Oral candidiasis in an adult or esophagal, bronchial, or pulmonary candidiasis.
7. Cryptococcosis or isosporiasis.
8. Cryptosporidiosis; pneumocystis carinii pneumonia; strongyloidosis causing infection beyond the GI tract; toxoplasmosis causing infections in organs other than the liver, spleen, or lymph nodes; disseminated histoplasmosis.
9. Mycobacterium infections other than TB, brucellosis, or leprosy.
10. Cytomegalovirus causing infection in internal organs other than liver, spleen, or lymph nodes; herpes simplex causing infection for longer than 1 month, or infections other than mucocutaneous; progressive multifocal leukoencephalopathy.
11. Chronic lymphoid intersititial pneumonitis.
12. Kaposi's sarcoma or non-Hodgkin's lymphoma.

SOURCE: Office of Technology Assessment, 1988.

**Figure 2-14.-Health Maintenance Organizations: Number of AIDS/ARC Cases[a]**



[a](n = 16) AIDS/ARC cases include individual and group members. Data were not available for two plans.
[b]Percentages may not total 100 due to rounding.
[c]Represents the number of responding companies.
[d]One HMO alone reported 940 AIDS cases.

SOURCE: Office of Technology Assessment, 1988.

$750,000 for the year; the other had 11 cases from September 1986 through September 1987 and forecast total costs of $700,000 for 1987. At both plans, no cases occurred among nongroup members. (An additional HMO that had reported caring for 940 AIDS-related cases since 1981 did not project 1987 costs, but estimated average lifetime costs of approximately $35,000.)[36]

*What Proportion of HMO Members With AIDS or ARC Were Found To Have a Preexisting Condition for AIDS?*—One non-federally qualified HMO reported that more than half of its individual members with AIDS or ARC were found to have a preexisting condition. According to State law and in contrast to the other insurers, this plan was obligated to provide services for preexisting conditions (without a waiting period) unless the applicant had deliberately misrepresented his or her health before joining the HMO (200). (Federally qualified HMOs may have grounds to disenroll members who misrepresent their health, but the HMO is obligated to provide medically necessary health services until membership is terminated.)

*What Plans Have the HMOs Made in Response to the Financial Impact of the AIDS Epidemic?*—Half of the respondents (8 of 16) reported no new plans in response to the AIDS epidemic. However, 5 of the 16 HMOs (31 percent) reported intentions to reduce their exposure in the individual and small group health markets (e.g., by introducing more restrictive underwriting guidelines) while two plans intend to expand HIV or other testing, two others are currently considering their AIDS-related policies, and one is withdrawing from the individual health market altogether (table 2-19).

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[36] Average lifetime cost is the total cost from time of diagnosis until death.

## Top 10 Most Costly Conditions: AIDS v. Other Major Illnesses

**Commercial Insurers.**—Individual and small group (i.e., individually underwritten) coverage is perhaps the health insurance sector most vulnerable to financial loss in the wake of an unanticipated AIDS epidemic. In an effort to put the costs of AIDS into context and evaluate its impact, OTA asked insurers to identify which 10 of 22 major diagnostic categories (including AIDS and related conditions) absorbed the greatest share of claims dollars for individually underwritten policies. Thirty-six (58 percent) of the 62 respondents were able to provide these data.

Six of 36 companies (17 percent) reported that AIDS was among the 10 diagnoses that accounted for the largest proportion of individually underwritten claims. Overall, AIDS and related conditions ranked sixteenth for commercial insurers. The complete list of diagnoses in order of the frequency with which they were ranked as top 10 are presented in table 2-25.

**Blue Cross/Blue Shield Plans.**—BC/BS plans were also asked which 10 of 22 major diagnostic categories (including AIDS and related conditions) absorbed the greatest share of claims dollars for individually underwritten policies. Eight of the fifteen respondents (53 percent) were able to provide these data.

Only two of eight plans (25 percent) reported that AIDS was among the 10 diagnoses that accounted for the largest proportion of individually

**Table 2-25.—Commercial Health Insurers: AIDS v. Other Major Illnesses**

The surveyed insurers were provided a list of 22 major diagnostic categories, including AIDS and related conditions, and asked to rank the ten diagnoses that account for the largest proportion of their total individually underwritten claims costs (see app. D, question III-D).

| Diagnostic category | Number of times diagnosis was ranked in the top ten (n=36)[a] |
|---|---|
| 1. Circulatory disorders, including: | 59[b] |
| Heart disease | |
| Essential hypertension | |
| Cerebrovascular disease | |
| Other circulatory disorders | |
| 2. Neoplasms, including: | 51 |
| Malignant neoplasm of trachea, bronchus and lung | |
| Malignant neoplasm of breast | |
| Other neoplasms | |
| 3. Respiratory disorders | 27 |
| 4. Digestive disorders | 25 |
| 5. Diseases of the female reproductive system | 25 |
| 6. Injury, poisoning and toxic effects | 24 |
| 7. Musculoskeletal/connective tissue diseases | 21 |
| 8. Kidney/urinary tract diseases | 15 |
| 9. Mental disorders | 15 |
| 10. Nervous system diseases | 14 |
| 11. Liver, gallbladder, pancreatic disorders | 14 |
| 12. Pregnancy, childbirth, and the puerperium | 12 |
| 13. Diabetes mellitus | 10 |
| 14. Congenital abnormalities/perinatal conditions | 9 |
| 15. Substance use/induced organic disorders | 8 |
| **16. AIDS AND RELATED CONDITIONS** | **6** |
| 17. Ear, nose, and throat diseases | 4 |
| 18. Eye diseases | 4 |
| 19. Diseases of the skin, subcutaneous tissue and breast | 4 |
| 20. Male reproductive system diseases | 4 |
| 21. Infectious and parasitic diseases | 1 |
| 22. Other endocrine and metabolic diseases | 1 |

[a] Only 36 of the 62 responding insurers (58%) were able to answer to this question.

[b] Some of the responding insurers ranked specific diseases (e.g., heart disease, malignant neoplasm of the breast) within the general categories of "circulatory disorders" and "neoplasms"; others were unable to report their claims experience at this level of detail. As a result, circulatory disorders and neoplasms appear in the top ten more than 36 times.

SOURCE: Office of Technology Assessment, 1988.

underwritten claims. Both are located in areas of high AIDS prevalence; one plan reported that AIDS and related conditions absorbed 9 percent of claims dollars, the other, 4 percent. Overall, AIDS and related conditions ranked fourteenth for BC/BS plans. The complete list of diagnoses in order of the frequency with which they were ranked as top ten are presented in table 2-26.

**Health Maintenance Organizations.**—The responding HMOs did not provide sufficient information to analyze their response.

**Table 2-26.—Blue Cross/Blue Shield Plans: AIDS v. Other Major Illnesses**

The surveyed plans were provided a list of 22 major diagnostic categories, including AIDS and related conditions, and asked to rank the ten diagnoses that account for the largest proportion of their total individually underwritten claims costs (see app. D, question III-D).

| Diagnostic category | Number of times diagnosis was ranked in the top ten (n=8)[a] |
|---|---|
| 1. Circulatory disorders, including: | 9 |
| Heart disease | |
| Essential hypertension | |
| Cerebrovascular disease | |
| Other circulatory disorders | |
| 2. Respiratory disorders | 8 |
| 3. Digestive system disorders | 8 |
| 4. Musculoskeletal/connective tissue diseases | 8 |
| 5. Neoplasms, including: | 6 |
| Malignant neoplasm of trachea, bronchus and lung | |
| Malignant neoplasm of breast | |
| Other neoplasms | |
| 6. Pregnancy, childbirth, and the puerperium | 6 |
| 7. Mental disorders | 6 |
| 8. Injury, poisoning, and toxic effects | 5 |
| 9. Congenital abnormalities/perinatal conditions | 5 |
| 10. Liver, gallbladder, pancreatic disorders | 4 |
| 11. Kidney/urinary tract diseases | 3 |
| 12. Nervous system diseases | 3 |
| 13. Diseases of the female reproductive system | 3 |
| **14. AIDS AND RELATED CONDITIONS** | **2** |
| 15. Infectious and parasitic diseases | 1 |
| 16. Blood diseases | 1 |
| 17. Ear, nose, and throat diseases | 1 |
| 18. Eye diseases | 1 |

[a] Only 8 of the 15 responding plans (53%) were able to answer to this question.

[b] Some of the responding plans ranked specific diseases (e.g., heart disease) within the general category of "circulatory disorders"; others were unable to report their claims experience at this level of detail. As a result, circulatory disorders appears in the top ten more than eight times.

SOURCE: Office of Technology Assessment, 1988.

## Chapter 3

# Employment Testing

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## Chapter 3

# Employment Testing

## INTRODUCTION

The focus of this assessment in the employment area is the use of diagnostic and predictive tests to screen for medical and health-related conditions among prospective employees in order to hold down health care costs. However, there are other reasons why employers might want to screen prospective as well as current employees.

First, screening may be used as part of a pre-employment evaluation to disqualify applicants (e.g., testing for use of illegal drugs such as marijuana and cocaine, or AIDS antibody testing) or to determine if the applicant can physically perform the intended work (e.g., examinations for firefighters and police). Second, after a person is hired, screening may be used to determine whether there is any health condition that may require special precautionary care because of known workplace exposures. Third, screening tests may be used to monitor workers exposed to known or suspected environmental hazards, including preplacement testing to establish a baseline that can be used for comparison with future worksite monitoring results. These examinations may be periodic (e.g., conducted on a yearly basis), episodic (e.g., conducted after an unusual exposure, such as an accidental spill of a hazardous substance), or conducted after returning to work following an illness or injury. Lastly, screening increasingly has been incorporated into workplace wellness programs to identify risk factors associated with disease so that risk factors can be reduced through health education.

By identifying applicants at risk for disease, especially chronic diseases, and not hiring them, employers would forego the expense of decreased productivity and of time lost from work (including the costs to hire and train workers to temporarily fill in for the absent employee). Employers who provide health insurance to their employees would also have reduced costs. These incentives to screen applicants may be much more significant for some employers than for others. For example, employers with low turnover and high training costs may be especially interested in preemployment screening. Similarly, employers with generous health care and disability benefits may be more inclined to screen than employers with limited benefits. Employers with high employee turnover may not have incentives to test for disease susceptibilities if new employees are young and likely to be employed elsewhere when these diseases become manifest. On the other hand, there might be greater incentives to test for illegal drug use if prospective and/or new employees are young, because of greater use of illegal drugs among the younger workforce.

In this chapter, information and issues concerning employment-based testing are first presented, followed by a similar analysis of the health benefits that are available through the workplace.

## LIMITS ON EMPLOYMENT-BASED TESTING

A wide variety of legal restraints is potentially applicable to employment-based screening, although much remains unsettled in this area. Distinctions must also be made as to whether the employer is in the public or private sector (i.e., whether governmental action is involved), and whether a cause of action by a prospective employee who objects to testing is grounded in an existing statute or in case law as developed over the years by the courts. Additionally, States differ in their approaches and available legal remedies, so the State in which a cause of action is brought may also have a substantial bearing on the success or failure of challenges to preemployment testing.

### Constitutional and Related Remedies

Resistance to screening based on constitutional restrictions is limited to public sector employees and government mandated testing of private contractors because of the requirement that State action must be involved before the constitutional remedies apply. The principal constitutional remedies are the Fourth Amendment limitations on search and seizure, Fifth Amendment prohibitions against self-incrimination, requirement of a "rational basis" for testing under the Fourteenth Amendment, and a general constitutional right to privacy.

Most of the litigation concerning these constitutional principles has involved the Fourth Amendment and urine drug screening programs. While requiring urine specimens is a search and seizure, it does not require a warrant and probable cause, but does require reasonable suspicion based on objective facts (179), or urine drug testing must be conducted only in narrow, specifically delineated circumstances (216).

A right to privacy may result in prohibiting testing when no particular basis exists for testing (41), but this may not be the case in closely regulated industries, such as horse racing, where testing without individual suspicion has been found to be reasonable (269). Some State constitutions may also contain a right to privacy (e.g., California, Illinois, Louisiana, Florida), and may be enforced even against private employers (105).

Some States have also enacted laws directed against specific testing programs. For example, California, Florida, Hawaii, Massachusetts, Texas and Wisconsin have limited use of AIDS antibody testing or information on antibody status in determining employability (168). In the case of urine drug testing, no State has prohibited its use, but several States have enacted laws determining when and under what circumstances such testing can be conducted. Connecticut, Iowa, Minnesota, Montana, Rhode Island, and Vermont have all enacted laws that require either probable cause or reasonable suspicion before testing can be conducted. Utah, on the other hand, enacted a law that seems to encourage drug testing as long as it is "fair and equitable" because it "is in the best interest of all parties." (See table 3-1 for State laws on AIDS, and table 3-2 for a summary of 1987 State legislative activities on urine drug testing.)

## Statutory Remedies

The principal statutory remedy available to persons objecting to employment-based screening is the Vocational Rehabilitation Act of 1973 (29 U.S.C. sections 701-796), which applies to Federal employment and employers receiving Federal funds. Over 40 States and the District of Columbia also have legislation prohibiting handicap discrimination in private sector employment, and while the definitions and judicial interpretations of what constitutes a handicap vary by State, about one-third follow the Federal law. Thirty-four States include AIDS patients in their definition of handicapped, while Georgia and Kentucky expressly exclude persons with communicable diseases (260).

Handicapped persons must be hired or continue to be employed if they can be reasonably accommodated and can perform their work without endangering the health and safety of other workers (29 C.F.R. section 1613.702(f)). In March 1987, the U.S. Supreme Court ruled that a person with tuberculosis was a handicapped person within the meaning of the law and that contagiousness did not automatically remove the person from the Act's protection, but also expressly stated that the Court was not ruling whether a person infected with the AIDS virus (i.e., an AIDS antibody-positive person without disease) would come under the Act's protection (259).

As for drug testing under the Vocational Rehabilitation Act, alcoholics or drug abusers may be considered handicapped within the meaning of the Act only if their abuse does not affect job performance or pose a direct threat to the property or safety of others. An applicant or employee who merely tests positive on a drug screening test probably is not protected by the Act, because a "physical or mental disability" is required (29 U.S.C. section 706(7)(A)), and drug use has not limited a major life activity. For example, in *McLeod* v. *City of Detroit* (180), the court found that a recreational user of marijuana was not handicapped, but that persons with a history of drug abuse were intended by Congress to be protected by the Act.

## Table 3-1.—State Legislation on AIDS[a]

| State | Antibody testing | Blood | Confidentiality | Employment | Housing | Informed consent | Insurance | Marriage | Prison population | Reporting |
|---|---|---|---|---|---|---|---|---|---|---|
| Alabama | | | | | | | | | | |
| Alaska | | | | | | | | | | |
| Arizona | | | | | | | | | | |
| Arkansas | | | | | | | | | | |
| California | CA | CA | CA | CA | CA | CA | CA | CA | | CA |
| Colorado | CO | | CO | | | CO | | | | CO |
| Connecticut | | | | | CT | | | | | |
| Delaware | DE | | | | | | | | DE | |
| DC | | | | | | | DC | | | |
| Florida | FL | FL | FL | FL | | | FL | | FL | FL |
| Georgia | | GA | | | | | | | | GA |
| Hawaii | | | HI | HI | HI | | HI | | | |
| Idaho | ID | | | | | | | | | ID |
| Illinois | IL | IL | IL | | | | | IL | | IL |
| Indiana | | | IN | | | | | | | IN |
| Iowa | IA | | IA | | | | | | IA | IA |
| Kansas | | | | | | | | | | |
| Kentucky | | | KY | | | | | | | KY |
| Louisiana | | | | | | | | LA | | LA |
| Maine | | | ME | | | | ME | | | |
| Maryland | | | MD | | | | | | | MD |
| Massachusetts | | | MA | MA | | MA | | | | |
| Michigan | | | | | | | | | | MI |
| Minnesota | | | | | | | | | | |
| Mississippi | | | | | | | | | | MS |
| Missouri | | | | | | | | | | |
| Montana | | | | | | | | | | |
| Nebraska | | | | | | | | | | |
| Nevada | | | | | | | | | NV | NV |
| New Hampshire | | | | | | | | | | |
| New Jersey | | | | | | | | | | |
| New Mexico | | | | | | | | | | |
| New York | | | NY | | | | | | | |
| North Carolina | | | | | | | | | | NC |
| North Dakota | | | ND | | | | | | | |
| Ohio | | | | | | | | | | |
| Oklahoma | OK | OK | | | | | | | | |
| Oregon | | | OR | | | | OR | | OR | |
| Pennsylvania | | | | | | | | PA | | PA |
| Rhode Island | RI | | RI | | | | | | | RI |
| South Carolina | | | | | | | | | | |
| South Dakota | | SD | | | | | | | | |
| Tennessee | TN | TN | | | | | | | | TN |
| Texas | TX | | TX | | | | | TX | | TX |
| Utah | | | | | | | | UT | | |
| Vermont | | | | | | | | | | |
| Virginia | VA | | | | | | | VA | | |
| Washington | | | | | | | | | | |
| West Virginia | | | | | | | WV | | | |
| Wisconsin | WI | | WI | WI | | WI | WI | | | WI |
| Wyoming | | | | | | | | | | |

[a] The information contained in this chart refers only to legislation and not to administrative regulations, AIDS indicates acquired immunodeficiency syndrome.

SOURCE: H.E. Lewis, "Acquired Immunodeficiency Syndrome: State Legislative Activity," *J.A.M.A* 258(170):2410-2414, Nov. 6, 1987.

## Table 3-2.—1987 State Legislative Activities on Urine Drug Testing

| | Enacted | Probable cause or reasonable suspicion | Rebuttal | Confirmatory test | Confidential | Discipline/ dismissal restricted | Employee remedies | Proposed | Probable cause or reasonable suspicion | Rebuttal | Confirmatory test | Confidential | Discipline/ dismissal restricted | Employee remedies | Other | None introduced |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Alabama | | | | | | | | | | | | | | | | AL |
| Alaska | | | | | | | | AK | AK | AK | AK | | | AK | | |
| Arizona | | | | | | | | AZ | | | | | | | | |
| Arkansas | | | | | | | | | | | | | | | | AR |
| California | | | | | | | | CA | CA | | CA | CA | CA | CA | | |
| Colorado | | | | | | | | CO | | | | | | | CO | |
| Connecticut | CT | CT | | CT | CT | CT | CT | | | | | | | | | |
| Delaware | | | | | | | | | | | | | | | | DE |
| Florida | | | | | | | | | | | | | | | | FL |
| Georgia | | | | | | | | GA | | | | | | | GA | |
| Hawaii | | | | | | | | HI | | | | | | | | |
| Idaho | | | | | | | | | | | | | | | | ID |
| Illinois | | | | | | | | IL | IL | IL | IL | IL | IL | IL | | |
| Indiana | | | | | | | | IN | | | | | | | IN | |
| Iowa | IA | IA | IA | IA | IA | IA | IA | | | | | | | | | |
| Kansas | | | | | | | | | | | | | | | | KS |
| Kentucky | | | | | | | | | | | | | | | | KY |
| Louisiana | | | | | | | | | | | | | | | | LA |
| Maine | | | | | | | | ME | ME | | ME | ME | ME | ME | | |
| Maryland | | | | | | | | MD | | | | | | | MD | |
| Massachusetts | | | | | | | | MA | MA | MA | MA | | | MA | | |
| Michigan | | | | | | | | | | | | | | | | MI |
| Minnesota | MN | MN | MN | MN | MN | MN | MN | | | | | | | | | |
| Mississippi | | | | | | | | | | | | | | | | MS |
| Missouri | | | | | | | | | | | | | | | | MO |
| Montana | MT | MT | MT | MT | MT | MT | | | | | | | | | | |

## Table 3-2.—1987 State Legislative Activities on Urine Drug Testing—Continued

| | Enacted | Probable cause or reasonable suspicion | Rebuttal | Confirmatory test | Confidential | Discipline/ dismissal restricted | Employee remedies | Proposed | Probable cause or reasonable suspicion | Rebuttal | Confirmatory test | Confidential | Discipline/ dismissal restricted | Employee remedies | Other | None introduced |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nebraska | | | | | | | | NE | NE | | NE | NE | NE | | | |
| Nevada | | | | | | | | NV | | | | | | | NV | |
| New Hampshire | | | | | | | | | | | | | | | | NH |
| New Jersey | | | | | | | | NJ' | NJ' | | NJ' | NJ' | NJ' | | | |
| New Mexico | | | | | | | | | | | | | | | | NM |
| New York | | | | | | | | NY | NY | | NY | NY | NY | | | |
| North Carolina | | | | | | | | NC | | | | | | | NC | |
| North Dakota | | | | | | | | | | | | | | | | ND |
| Ohio | | | | | | | | | | | | | | | | OH |
| Oklahoma | | | | | | | | | | | | | | | | OK |
| Oregon | | | | | | | | OR | OR | | OR | OR | OR | | | |
| Pennsylvania | | | | | | | | PA | PA | | PA | PA | PA | | | |
| Rhode Island | RI | RI | RI | RI | | | RI | | | | | | | | | |
| South Carolina | | | | | | | | | | | | | | | | SC |
| South Dakota | | | | | | | | | | | | | | | | SD |
| Tennessee | | | | | | | | TN | | | | | | | TN | |
| Texas | | | | | | | | TX | | | | | | | TX | |
| Utah | UT | | UT | | | | UT | | | | | | | | | |
| Vermont | VT | VT | VT | VT | VT | VT | VT | | | | | | | | | |
| Virginia | | | | | | | | | | | | | | | | VA |
| Washington | | | | | | | | WA | WA | WA | WA | WA | WA | WA | | |
| West Virginia | | | | | | | | | | | | | | | | WV |
| Wisconsin | | | | | | | | WI | | | | | | | WI | |
| Wyoming | | | | | | | | WY | | | | | | | WY | |
| Total | 7 | 6 | 6 | 6 | 5 | 5 | 6 | 23 | 11 | 4 | 11 | 9 | 9 | 6 | 10 | 20 |

SOURCE: S.M. Bannister, "State Statutes Regulating Drug Testing of Private Employees," paper presented at Continuing Legal Education with the University of Kansas on "Drug Testing: Facts, Fears, and Policy Perspectives," Lawrence, KS, Nov. 5, 1987.

Title VII of the Civil Rights Act of 1964 (29 U.S.C. section 2000e et seq.), which prohibits discrimination on the basis of race, sex, national origin, and religion, might also apply in limited circumstances, as when testing has a "disparate impact" on members of a protected group. Testing would have to have a "manifest relation to the employment in question" (71), and there must not be available a less discriminatory method that the employer could use (114). The U.S. Supreme Court has ruled in one case that might have found the Civil Rights Act to be applicable, but found that it was not. The New York City Transit Authority disqualified all driver applicants who were on methadone maintenance for heroin addiction. Despite the fact that 81 percent of applicants were either black or Hispanic, the Supreme Court upheld the constitutionality of the Transit Authority's decision (221).

## Other Employee Remedies

Most of the following discussion is limited to employees who are represented by unions—that is, these remedies are not available to job applicants and nonunionized employees— with employee rights based on: 1) a duty to bargain with the union before implementing testing programs, and 2) a just cause determination before termination of employment based on positive testing results.

The National Labor Relations Act makes it an unfair labor practice for employers to refuse to bargain with employee representatives over terms and conditions of employment (Sections 8(a)(5) and 8(d)), and issues concerning worker safety are a mandatory subject of collective bargaining (286). However, a union might be found to have waived its bargaining rights by express language in its contract, by the history of bargaining between the union and the employer, and/or past practice, and courts and arbitrators have been inconsistent in litigation over this issue (105).

Termination of employment will be upheld when it is called for in the contract and when drug testing is conducted under a negotiated program. Moreover, termination has generally been upheld when: 1) the test was conducted when an employee was involved in an accident, 2) when there was a reasonable basis to believe the employee was under the influence, or 3) when the employee had a known substance abuse problem (105)—that is, when the drug testing program was not on a random basis. In addition, arbitrators have tended to require a greater burden of proof for drug-related discharges, then in discharge cases generally, because of the stigmatization of drug use and resulting difficulty in finding other employment (17). For example, some arbitrators have used the standards of "clear and convincing evidence" or "beyond a reasonable doubt" instead of the more easily met standard of "preponderance of the evidence" (19,176). In "mixed motive" cases—for example, when the employer claims that an employee was fired because of a positive drug test when the real reason might be that the employee was actively engaged in union activities—the employer must prove that the action would have occurred regardless of the protected activities (17,150).

Generally, the following steps must be taken if employees are to be discharged for drug (and alcohol) use (250):

1. the employee must have had notice of the prohibition and the corresponding penalty,
2. the rules must have been applied fairly,
3. management must have investigated the charges and given the employee a reasonable chance to answer them, and
4. the punishment must fit the crime.

Absent some non-union-based recourse (e.g., drug use as a handicap), nonunionized employees can be terminated at will by their employers when their drug tests are positive. There may be a small possibility, however, that the court may find an employer liable for wrongful termination when such drug-testing-based termination is against "public policy." While no cases have been litigated on this theory for drug testing, two State courts have reached opposite conclusions when polygraph testing was at issue. An Illinois court saw no clearly expressed Illinois public policy against polygraph testing (48) while a West Virginia court did, despite each employee's written consent to take the test (52).

## Tort Law

Some tort law remedies might be available to prospective and current employees. These potential remedies are most applicable to drug testing and are generally applicable only when employers engaged in outrageous practices.

Similar to, but distinct from the general constitutional right of privacy, is invasion of privacy. A successful claim would have to show intentional intrusion on the private affairs of the plaintiff in a manner that would be highly offensive to a reasonable person (231). Consenting to the intrusion, or when the employer has a legitimate interest in testing and acted reasonably, would defeat a claim based on invasion of privacy.

Tort challenges may be avoided through the following procedures (105):

1. publishing the employer's reasons why testing is necessary,
2. providing advance notification before implementing a testing program,
3. obtaining written consent from employees subject to testing,
4. limiting disclosure of test results only to those who need to know, and
5. making testing as least intrusive as possible.

# THE EXTENT OF MEDICAL TESTING BY EMPLOYERS

## Medical Examinations

Perhaps the most prevalent type of medical screening required by employers is the general physical examination, including routine medical tests. This requirement is not new, but the National Institute for Occupational Safety and Health (NIOSH) has reported that the percent of employers who require job applicants to pass medical screening examinations increased from 38.5 percent of employers in the early 1970s to 49 percent in the early 1980s. The percent of employers requiring periodic medical exams of their employees also increased over the decade from 14.4 percent to 30.1 percent, and about one-third of collective bargaining agreements include provisions for employee medical examinations and testing (249).

Among private businesses, company size and industrial sector are associated with employee medical examination policies. According to NIOSH's National Occupational Hazard Survey data from 1972-74, 83 percent of companies with more than 500 employees used a pre-employment medical examination, compared with 49 percent of companies with 250 to 500 employees, and 19 percent of companies with fewer than 250 employees (248). In all plant size categories, employers were more likely to require pre-employment or pre-placement screening rather than periodic monitoring. For example, in large companies (more than 500 employees), where an estimated 83 percent of employees went through pre-employment screening, 65.4 percent were subjected to periodic monitoring (238). A second survey conducted by NIOSH from 1981 through 1983 (the National Occupational Exposure Survey), indicated that the percent of employees who were subjected to pre-employment examinations and periodic monitoring had not changed substantially since the 1972-74 period (238). Companies with industrial hygiene and safety programs, and/or unionized companies, were more likely to provide medical screening than other companies (238).

Variations in the prevalence of medical testing by industry also were relatively consistent in the two surveys. In both surveys, employees in transportation and public utility industries were most likely to have pre-employment examinations; an estimated 82 percent of these employees in 1972-74 and 73 percent in 1981-83. In 1972-74, the manufacturing industry ranked second in pre-employment screening (67 percent of employees screened), followed by the services industry (41 percent screened). In 1981-83, the services industry was second (69 percent of employees screened), followed by the manufacturing industry (62 percent screened).

The two NIOSH surveys included about 4,500 workplaces throughout the United States that were selected to represent a range of plant sizes and industry types; but they excluded mining, agriculture, Federal and State governments, and businesses not covered by the Occupational Safety and Health Act. Therefore these surveys, which provide the only representative national sample data on medical screening in the workplace, are limited in themselves and do not specifically address the types of diagnostic and predictive medical testing that are the focus of this assessment. The surveys did determine the frequency of blood and urine testing in workplace screenings, although they did not identify the specific types of blood and urine testing that was conducted.

The frequency of laboratory testing in employee screening examinations also varied with company size and industry. An estimated 14.7 percent of all workers who had periodic medical examinations in 1972-74 had blood tests, but in the primary metal industries, the figure was 55.4 percent. Urine testing was included in medical screening for 14.4 percent of all workers and up to 46.7 percent in petroleum and coal product workers in the early 1970s (238, 248). The use of both blood and urine tests in periodic medical screenings increased substantially from 1972-74 to 1981-83. In 1981-83, it was estimated that 36 percent of all workers had blood tests and 35 percent had urine tests. In plants employing more than 500 workers, periodic medical screening in 1981-83 included blood and urine testing for 69 and 66 percent of all workers, respectively. Blood testing was most prevalent in the service industries, where an estimated 60 percent of the workers were screened (238).

In order to examine current levels of pre-employment and periodic medical screening in greater detail, data on testing practices by private and government employers as reported in the literature and in recent surveys are summarized below for genetic testing, drug testing, and AIDS antibody testing.

## Genetic Testing

One in four workers has been estimated to be exposed to federally regulated hazardous substances in the workplace (12). If this is true, it would appear that biological screening and monitoring could be clearly beneficial to employees in some work settings. However, views about the value of genetic testing depend on whether the tests are used in pre-employment screening, in which case test results could be used to discriminate against job applicants, or in periodic monitoring, which may be extremely costly to employers.

Genetic testing to screen individuals for hypersusceptibility to hazardous materials has been controversial in the past, because genetic traits frequently are associated with particular racial or ethnic backgrounds. The Dupont corporation's routine screening of all black job applicants for sickle cell anemia trait, initiated in 1972, drew so much criticism as a discriminatory practice when it was reported in 1980 that it was discontinued (12,163). Florida, Louisiana, and North Carolina specifically prohibit sickle cell testing; and New Jersey prohibits testing for sickle cell and other genetic traits (e.g., Louisiana Rev. Stat. Ann., Section 23:1002(A)(1) West Supp., 1984-85).

A 1982 study by the Office of Technology Assessment (OTA) on the extent of genetic testing in the 500 largest U.S. industrial companies, 50 of the largest private utilities, and 11 large labor unions, found that of the 366 (65.2 percent) organizations responding, 6 (1.6 percent) were currently conducting genetic testing, 17 (4.6 percent) used some of the tests in the past 12 years, 4 (1.1 percent) anticipated using the tests in the next 5 years, and 55 (15 percent) stated they would possibly use the tests in the next 5 years (290). Most of the respondents in the OTA survey were large companies in the manufacturing, mining, or chemicals industries, or in utilities, as noted above. Response to this survey was voluntary, and therefore does not represent the extent of genetic testing by employers nationally.

In 1986, OTA completed a survey of biotechnology companies that were developing or were likely to develop genetic tests for commercial use based on recombinant DNA methods. A questionnaire was mailed to 120 biotechnology companies, and 85 of them responded (291). Twenty companies indicated they were developing such tests, and 16 completed a second, more detailed questionnaire. Of these, 12 were developing or planning to develop tests (4 had changed their plans since the first survey).

When asked to rate the sites where they expected use of genetic tests to be most important in 1990, the 14 companies rated the following sites in descending order of importance: genetic clinics, health department clinics, health department screening programs, prepaid health groups, private primary care practices, sites such as reference and DNA labs, insurance companies, the military, places of employment, private nongenetic specialty practices, correctional institutions, public schools, and homes. Five of the twelve companies thought it likely by the year 2000 that insurance companies would be using genetic tests on applicants. Other sources predict that by the year 2000, most people will be getting genetic profiles, possibly through their place of employment, and one company is reported to be testing an employee "wellness" evaluation program that involves computer analysis of family histories and 32 different blood tests for susceptibility to a range of diseases (311).

There was disagreement among respondents to the 1986 OTA survey over whether genetic testing should be mandated under certain circumstances. Seven of twelve companies that were developing tests disagreed with the statement that genetic tests should be required for marriage licenses; but a majority of them (8 of 12) believed mandatory genetic testing may be likely by the year 2000. Although most respondents did not rate places of employment as an important site for genetic testing in 1990, 5 of 12 thought it likely that employers would be using genetic tests to screen job applicants by the year 2000. Seven of twelve agreed that the health risks identified by genetic testing could be used appropriately to exclude susceptible workers from hazardous jobs; 9 of 12 thought this use likely by 2000.

In November 1985, the Harris organization conducted a survey on genetic testing by employers and posed the question: Should an employer have the right to force a job applicant to undergo testing for a genetic disorder that would not become symptomatic for 20 years? Of 1,254 adults surveyed, only 11 percent answered "yes" to that question. Only 15 percent of the respondents felt an employer's knowledge of a job applicant's future serious disease was acceptable grounds for that candidate to be denied work. On the other hand, if testing was oriented to diagnosing and curing disease rather than to employment or insurance decisions, about 50 percent of the respondents were willing to be tested for incurable and fatal diseases they would develop later in life (38).

## Drug Testing

Various surveys have documented the increasing tendency of both private and public sector employers to screen applicants and to test employees for use of illegal drugs and prescription drugs that are commonly abused. Based on these surveys, perhaps half or more of employers, especially large employers, now test or plan to test for drug use.

The percent of Fortune 500 companies requiring urine drug testing for job applicants and/or current employees increased from about 10 percent in 1982, to approximately 25 percent in 1985, to an expected 50 percent in 1987 (249).

In a 1986 survey by the College Placement Council of its member employers who recruit on college campuses, a clear trend was found in the past 2 to 3 years to implement drug screening programs for job applicants. Of 497 respondents, 140 (28.2 percent) screened applicants, and an additional 97 (19.5 percent) employers planned to implement screening within the next 6 to 24 months (266).

In descending order, the most common reasons given for drug testing among these 140 companies were concerns over workplace safety (by far the most important reason); security; quality/reliability of products; quality of service; increased productivity; control of medical costs; and law, government, or noncompany regulations. The types of employers most likely to test applicants were utilities (37.1 percent); chemicals, drugs, and allied products (9.3 percent); aerospace (8.6 percent); and petroleum and allied products (7.9 percent). Nearly all (131 of 140) screened all applicants, whether for management, clerical, or technical positions, and most screened applicants whether they were seeking full-time, part-time, or temporary positions.

Eighty of the 140 companies used only a screening test, while 53 also performed confirmatory testing before informing applicants that they had tested positive for drug use. Nearly all (124 of 140) used a positive test to exclude applicants, although 105 allowed those who failed the test to reapply at a later time.

In a 1987 survey of more than 2,000 employers (91 percent in the private sector) (37), among employers with more than 500 employees, 23 percent tested applicants, and 17 percent tested employees. Among companies with 100 to 500 employees, 14 percent tested applicants, and 7 percent tested employees. Among the large employers, 47 percent in the transportation industry tested, as did 17 percent of those in manufacturing. More than half of those not currently testing were considering it. These trends were found despite the fact that less than 1 percent of employers identified drug abuse as the most serious problem in the workplace. As in other studies, however, larger employers—22 percent in this survey—considered drug abuse as a serious problem in the workplace.

Indirect evidence was also found in this survey that supported the finding in the 1986 College Placement Council survey that most employers were using only screening tests—and not confirming tentative positive results with more specific methods such as gas chromatography/mass spectrometry—before concluding that the applicant was a drug user. Costs of testing job applicants ranged from $10 to $29 per urine specimen for more than half of the employers, while only 25 percent of employers had costs of $70 or more per specimen.

Numerous efforts are also being made at various levels of government to implement or expand drug testing programs, particularly among employees involved in public safety (e.g., police, firefighters), public transportation (e.g., airline pilots, air traffic controllers, bus drivers), and public health (e.g., public health physicians and nurses). Many of these efforts are under legal challenges by employees, labor unions, and the American Civil Liberties Union (ACLU). Opponents generally have not challenged probable cause testing, but have objected to:

- mandatory and/or random testing;
- inclusion of the entire work force or broad classes of workers in testing programs; and
- unilateral decisions by public agencies to implement testing without negotiating with unions on whether testing should be initiated, the details of the testing program, and the effects on employees who test positive (e.g., what sanctions should be imposed, and what rehabilitative services will be offered).

At the Federal level, a June 1986 report by the U.S. House of Representatives' Subcommittee on Civil Service, Committee on Post Office and Civil Service, reported that drug testing was already being conducted by the Army, Air Force, Navy, Federal Aviation Administration (in the Department of Transportation), Secret Service (in the Department of the Treasury), and Customs Service (288).

In September 1986, President Reagan issued an Executive Order (310) directing all Federal agencies to institute:

- random urine drug testing programs for employees in sensitive positions,
- reasonable suspicion testing,
- incident-based testing,
- testing as a followup to rehabilitation, and
- job applicant testing.

Subsequently, the Office of Personnel Management issued advisory Federal Personnel Manual Letters in November 1986 (312) and again in March 1987 (313) to assist Federal agencies in implementing the President's order. The Department of Health and Human Services issued Scientific and Technical Guidelines to Federal agencies in February 1987, and published a revised version of these guidelines as proposed regulations in August 1987 (307), with final publication expected by December 31, 1987.

The Department of Transportation (DOT), because it already had drug testing programs for some of its branches (e.g., the Federal Aviation Administration), implemented random testing in September 1987 for all DOT employees with security clearances of top secret or higher, as well as for air traffic controllers, flight test pilots, electronic technicians, firefighters, civil aviation security specialists, aviation safety inspectors, railroad safety inspectors, Coast Guard drug enforcement personnel, vessel traffic controllers, and motor vehicle operators.

An attempt to win a temporary restraining order by the American Federation of Government Employees was denied by a Federal judge (201). Similar attempts by the National Treasury Employees Union to prohibit implementation of the President's Executive Order until the merits of the issue could be decided by the courts were denied (216).

However, in March 1988, a U.S. District judge in the District of Columbia ruled that the U.S. Army's mandatory random drug testing of civilian employees was unconstitutional, ruling that urinalysis cannot show actual impairment and that the Army's "nonsafety" interests in ensuring a drug-free work force did not warrant overriding Fourth Amendment protections against unreasonable searches (316). The judge's decision was based on the U.S. Court of Appeals for the District of Columbia's ruling a few months earlier that, while drug testing of DC school transportation employees to determine if workers were impaired by drugs was not unconstitutional, urinalysis could not measure impairment. Two days earlier, the U.S. Supreme Court had agreed to consider the National Treasury Employees Union suit that attacked the constitutionality of the Executive Order (215), and which the 5th U.S. Circuit Court of Appeals had upheld (216). Thus, conflicting rulings among different circuits of the U.S. Court of Appeals will now be resolved by the U.S. Supreme Court.

## AIDS Antibody Testing

The U.S. Supreme Court decision in March 1987 on the *Arline* case indicates that full-blown AIDS will be considered a disability under Federal anti-discrimination statutes and thus will not be acceptable grounds for discrimination in employment. (The Supreme Court decision also runs directly counter to a Justice Department opinion issued just prior to the *Arline* decision that concluded that even unfounded fears by other workers would be legitimate grounds for employers to discharge employees with infectious diseases.) It is not clear how this decision affects those who are infected with the AIDS virus but do not have the disease. Other issues that American corporations will have to deal with in relation to AIDS in the workplace include the following (16):

- confidentiality of employees' health data, which is protected in most States;
- the right of AIDS victims to work, as long as they want to work and are able to work, because, in addition to the *Arline* decision, almost all States prohibit discrimination against individuals with physical handicaps and disabilities, including AIDS;
- employer-provided benefits and insurance, which provide essential access to medical care for AIDS patients;
- AIDS antibody testing policies;
- fears of contagion among co-workers and the employer's obligation to provide a safe workplace;
- the needs of companies to avoid financial and legal exposure; and
- the effects of AIDS on worker productivity.

### Current Policies on AIDS in the Workplace

According to the Centers for Disease Control (CDC), there is no justification for excluding AIDS or antibody-positive individuals from the workplace on the grounds of risks to coworkers, and CDC also recommends against routine testing in the workplace (204). These conclusions have been supported by the American Medical Association (AMA) (9). On October 30, 1987, the U.S. Departments of Labor and of Health and Human Services issued a joint advisory notice to health-care employers on procedures to be followed on "Protection Against Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)" (307).

In the Federal Government, mandatory AIDS testing has been instituted for all military service applicants and active duty personnel (since October 1985), foreign service employees of the State Department since November 1986, and participants in the Job Corps since December 1986. Additionally, in the summer of 1987, the Public Health Service (PHS) classified AIDS as a "dangerous contagious disease" for immigration and naturalization actions, and the U.S. Senate unanimously passed a requirement for negative AIDS antibody status for immigrants seeking admission to the United States.

Numerous surveys have been conducted on the experience of private employers with AIDS among their workers and on their response to AIDS. These surveys reveal that employers are increasingly encountering AIDS among their workforce. For example, in a January 1986 survey, 18 of 238 employers (8 percent) had known cases of AIDS among their employees (8 of these 238 employers had tested their employees for AIDS antibodies, while 2 had tested job applicants) (46). Another survey reported at the same time showed that 34 of 154 large companies (22 percent) had workers with AIDS (46). In a March 1987 survey, 29 percent of 600 companies had known AIDS cases among their employees (119). In another survey conducted in summer 1987 among 151 Fortune 500 companies, 33 percent of the companies had employees with AIDS, and another 50 percent expected to encounter AIDS in the near future (169).

Generally, companies have rejected AIDS antibody testing for job applicants and employees, but a significant percent of senior management support testing. In a 1985 survey of 861 large private firms, 2 percent of surveyed employers stated that they screened job applicants for AIDS, while another 10 percent were considering it. Those who screened or were considering it were more concentrated in the southeastern United States (120). In a March 1987 survey of 600 companies (see above), 87 percent of the personnel and benefits administrators stated that they had considered AIDS antibody testing for job applicants, while 9 percent had actually conducted testing. Sixty-two percent of the respondents felt that management would oppose testing for all job applicants, and 15 percent were not sure; but 23 percent felt that management would favor pre-employment testing (119).

Similar results were obtained in another survey conducted in late 1987 (152). Among 101 companies employing between 1,000 to 10,000 people, two-thirds of the companies did not believe that testing would stem the spread of AIDS in the workplace or help control benefit costs. Support of testing also seemed to be inversely related to knowledge of AIDS. Only about one in five (19 percent) of companies that claimed they were extremely or very knowledgeable about AIDS supported testing; 37 percent of companies who reported being somewhat knowledgeable supported testing; and half of companies not very knowledgeable about AIDS supported testing.

Employers generally support education as the best way to deal with AIDS among their employees. However, there is a substantial gap between what employers think should be done versus actually developing educational strategies and programs for their employees. For example, in a survey of Fortune 1000 companies by National Gay Rights Advocates during the winter of 1986-87, of the 164 personnel directors responding (a total of 995 companies were asked to participate), only 30 (18 percent) had written policies on AIDS, and 8 more companies were developing AIDS policies (214). In the March 1987 survey of 600 companies (see above), only 15 percent had an AIDS education program in place (119). In the summer 1987 survey of 151 Fortune 500 companies (see above) in which 33 percent already had AIDS among its workforce and another 50 percent expected to encounter AIDS in the near future, only 40 percent of the surveyed companies had instituted AIDS information programs for their employees, and fewer than 20 percent had developed policies to help their employees with AIDS (169). In the late 1987 survey of 101 companies (see above), 82 percent strongly believed that companies should be educating their employees about AIDS, but only 28 percent were informing their employees about AIDS or what the company had done to deal with AIDS (152).

Employers also generally have treated AIDS among their employees as they have treated other illnesses. For example, this is the policy of the U.S. Office of Personnel Management (OPM). (See box 3-A for OPM's position on health and life insurance.)

Many employers who find they have employees with AIDS try to accommodate those individuals so that they can continue to work as long as possible and keep their health benefits coverage through the company's plan (152,169,214). In one survey, if a coworker objected to working with an employee with AIDS, 8 percent of respondents said they would move the employee with AIDS; 14 percent would move the coworker; 29 percent would insist that the situation continue unchanged; and 3 percent would take none of these actions. Forty-six percent were not sure what they would do (119).

Finally, there are indications that AIDS-related health care (and disability and life insurance) costs may be increasing for some employers as more of their employees develop AIDS. In a 1985 survey, the costs of treating AIDS patients, while quite high for the individual patient, did not appear to be a major issue for employer health plans (120). However, in a survey in late 1987, companies with AIDS cases reported an increase in expenditures for health care from AIDS of 4.5 percent, with expenditures for AIDS expected to increase an additional 16 percent by 1990 (152). The highest percentage increases among these companies were for life insurance costs, up nearly 28 percent from AIDS, but employers expected to gain more control over these costs so that increases in life insurance costs would be limited to 7 percent by 1990.

Further information on employer responses to AIDS are summarized in the next section.

### Box 3-A.—U.S. Office of Personnel Management Policy on Insurance and AIDS

HIV-infected employees can continue their coverages under the Federal Employees Health Benefits (FEHB) Program and/or the Federal Employees' Group Life Insurance (FEGLI) Program in the same manner as other employees. Their continued participation in either or both of these programs would not be jeopardized solely because of their medical condition. The health benefit plans cannot exclude coverage for medically necessary health care services based on an individual's health status or a pre-existing condition. Similarly, the death benefits payable under the FEGLI Program are not cancelable solely because of the individual's current health status. However, any employee who is in a leave-without-pay (LWOP) status for 12 continuous months faces the statutory loss of FEHB and FEGLI coverage but has the privilege of conversion to a private policy without having to undergo a physical examination. Employees who are seeking to cancel previous declinations and/or obtain additional levels of FEGLI coverage must prove to the satisfaction of the Office of Federal Employees' Group Life Insurance that they are in reasonable good health. Any employee exhibiting symptoms of any serious and life-threatening illness would necessarily be denied the request for additional coverage.

SOURCE: C. Horner, Director, U.S. Office of Personnel Management, Memorandum on "Acquired Immune Deficiency Syndrome (AIDS) in the Workplace: Guidelines for AIDS Information and Education and for Personnel Management Issues," Washington, DC, March 1988.

## EMPLOYER-PROVIDED HEALTH BENEFITS

The single most important source of health insurance for Americans is private coverage offered to workers and their dependents by employer-based health benefit plans. In addition to health insurance, employee benefits include life insurance, disability insurance, and paid time off for sick leave and vacations that represent nonwage (and hence, non-taxable) income for workers.

For a substantial share of workers with employer-provided health benefits, the employer still pays the insurance premiums for a comprehensive package of inpatient and outpatient services (or full costs, if the company is self-insured), often including mental health services, dental care, and vision care. With the high rates of health care cost inflation since the mid-1970s, however, and the increased health insurance premiums that have accompanied these rates, employers increasingly have sought ways to shift more of the costs to their employees. This trend has been pronounced since 1980, to the extent that health care cost containment is now a major objective of most companies that provide health care benefits for their employees.

In this cost containment environment, questions have been raised over how employers might respond to the ability to identify and exclude workers and prospective workers who may or would be likely to have exceptionally high health care costs, such as drug or alcohol abusers, or individuals with AIDS, ARC, or HIV infections. Employee drug testing, and especially pre-employment screening for drug use, have become relatively common, particularly among large businesses. How employers will deal with AIDS-related illnesses in the future is not yet clear (see above).

## Information on Employee Health Care Benefits

Data sources on employer-provided health benefits do not specifically address the issue of testing for genetic conditions, drug use, or HIV infections. The few questions relating to services for these conditions deal primarily with availability of drug and alcohol therapies and mental health services in employee assistance programs. Other sources suggest, however, that case management approaches such as are being applied to a variety of high-cost cases are being considered for AIDS patients, who would also benefit from expanded nursing home, hospice, and home health care services.

The only surveys of employee benefits in the private sector, including health benefits, that is based on a selected, nationally representative sample that has been repeated consistently in order to detect trends, are the surveys conducted by the U.S. Department of Labor's Bureau of Labor Statistics. This survey was initiated in 1979 and conducted annually since then. The survey was designed to provide data to the U.S. Office of Personnel Management on employee benefits in the private sector, as part of a new approach to evaluating the pay and benefits of Federal employees. The survey covers approximately 1,500 medium and large private sector firms that paid for employee benefit plans wholly or in part. The survey excludes firms that do not offer health and other employee benefits. The minimum size for included firms is 50, 100, or 250 employees, depending on the industry, and only full-time employees are counted. Thus, the surveys focus on large firms: 61 percent were companies with 1,000 or more employees, and 6 percent of the company plans covered at least 25,000 workers. Union and nonunion firms are included. The industries were grouped as follows: 1) mining; 2) construction; 3) manufacturing; 4) transportation, communications, electric, gas, and sanitary workers; 5) wholesale trade; 6) retail trade; 7) finance, insurance, and real estate; and 8) selected services.

An analysis of a sub-sample of the 1979 and 1984 surveys, based on data from 209 employee health plans in 173 companies that participated in both surveys, found that most employers had (98): 1) increased employee shares of costs, 2) modified plans to encourage use of less costly services, and/or 3) improved some benefits (e.g., more than half of the 209 plans increased the maximum lifetime payments under major medical plans).

In the 5 years between the 1979 and 1984 surveys, all but 11 of the 209 health benefit plans changed at least one feature. Plans were frequently redesigned to reduce basic coverage. More than one-fifth increased the deductible (the amount paid out-of-pocket by employees) in major medical policies, after which the plans typically paid 80 percent of covered charges, leaving 20 percent copayment by the employee. Twenty-eight plans eliminated first dollar coverage for surgery by 1984, and 91 plans (44 percent) required second opinions before elective surgery. Some plans provided more coverage for alternatives to costly inpatient care; for example, 34 plans increased coverage for extended care facilities (non-custodial care in a nursing home), and 62 plans introduced home health care benefits. Eleven of the 209 plans offered the option of coverage through health maintenance organizations (HMOs) in both 1979 and 1984.

In both 1979 and 1984, the majority of employers paid all of the health insurance premiums for their employees. However, for those plans requiring employee cost-sharing, employee contributions nearly doubled in the 5-year period. Finally, employers sought to contain health care costs not only by modifying their plans, but also by changing their methods of funding. Although commercial insurers (and Blue Cross/Blue Shield (BC/BS)) continued to be the most common method of funding benefits, the number of self-insured major medical plans more than doubled between 1979 and 1984, from 27 to 65.

In the most recent Bureau of Labor Statistics (BLS) survey conducted in 1986 (309), large and medium sized firms, which traditionally have been the most generous in providing employee benefits, offered health insurance benefits to 95 percent of their employees. Virtually all employees with health insurance (99 percent) were covered for hospital care, physician care, diagnostic laboratory and x-ray studies, prescription drugs, and private duty nursing. Only 54 percent of employees were covered entirely at their employers' expense, compared with 61 percent in 1985. The percent of employees with fully paid coverage for their families declined from 42 percent in 1985 to 35 percent in 1986. In 1986, employee contributions averaged $13 and $41 per month for individual and family coverage, respectively, an increase of 6 and 8 percent, respectively, from 1985. In contrast, modest increases in the percent of employees covered for alcoholism treatment (from 68 to 70 percent) and for drug abuse treatment (from 61 to 66 percent) occurred between 1985 and 1986.

The trend to less expensive nonhospital care continued in 1986. The availability of home health care increased from 56 to 66 percent of plan participants between 1985 and 1986; hospice care coverage rose from 23 to 31 percent. Enrollment in HMOs and preferred provider organizations (PPO) increased; enrollment in such programs were 5 percent in 1984, 7 percent in 1985, and 13 percent in 1986. Coverage by commercial insurers and BC/BS declined from about 80 percent of employees in 1980 to 50 percent or less in 1986. Self-insured plans for major medical plan participants increased from 38 percent in 1985 to 45 percent in 1986.

The Bureau of Labor Statistics has noted that the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) could affect many employer-provided health insurance plans. (COBRA requires extension of health plan coverage for at least 18 months for terminated or laid-off workers, who would pay up to 102 percent of premium costs.) BLS noted that its 1986 survey was conducted immediately prior to the enactment of COBRA. In the 1986 survey, 46 percent of participants were in firms which either discontinued insurance immediately upon layoff, or which had no established policy. Thirty-four percent were eligible for coverage paid at least in part by employers, and most of the remaining participants could continue coverage at their own cost. However, regardless of financing, continuation periods were usually 6 months or less, and only 4 percent were in plans that extended health insurance coverage indefinitely (308). (Group health insurance coverage continued after retirement for 72 percent of employees.)

Because factors such as employer size, location, and industry can affect the types and extent of health benefits offered, and because of business concerns over health care cost inflation, a number of private surveys of employer-provided health benefits have been conducted. Many of these surveys have focused on benefit costs and the prevalence of cost-containment activities. The results of these surveys are generally similar to the BLS surveys.

A January 1986 survey of 861 large private companies (also summarized above for their AIDS policies (120)), based on 1985 data, found that most companies had shifted more costs to employees through increased cost-sharing and incentives to use less expensive services and settings. Fifty-six percent of the surveyed companies offered at least one HMO/PPO option.

Surveys were conducted from 1979 through 1984 on 250 major private employers, 68 percent in the Fortune 100 companies, and 32 percent in the Fortune 500 companies, and covered medical and other benefit plans for salaried employees only (132). The report did not specifically address AIDS, pre-employment screening, or self-insurance (although given the large size of the firms surveyed, it is likely that the majority did self-insure), but focused on health care cost containment efforts in the private sector. Major findings on trends in employer-provided health benefits were as follows:

1. there was significantly more employee sharing of hospital and surgery costs in 1984—the percent of plans with 100 percent reimbursement for hospital care declined from 89 percent in 1979 to 50 percent in 1984;
2. there were significant increases in front-end deductibles—52 percent of the plans required them in 1984, compared with 17 percent in 1979;
3. there were dramatic increases in annual deductible amounts, with maximum deductibles set per family;
4. the use of maximum employee out-of-pocket limits increased to the point that in 1984, 86 percent of the plans had such limits; and
5. by 1984, more plans included incentives for employees to make less costly health service choices.

Similar surveys in 1985 and 1986 (133) showed continued trends in cost containment. In the 1986 survey, which included 812 major U.S. employers, 64 percent of the companies required front-end deductibles for medical expenses, up from 54 percent in 1985. The most common deductible was $100 per employee per year (in 32 percent of companies), but the trend was to higher deductibles; for example, $150 and $200 per year. Among the most common cost containment strategies were incentives for outpatient surgery (54 percent of plans), second surgical opinions (57 percent of plans), and outpatient tests prior to hospital admission (49 percent of plans).

A 1986 survey included nearly 1,500 employers in 36 States that responded voluntarily to a questionnaire mailed through local business coalitions (151). The companies employed about 4.4 million employees. The survey asked about overall health care costs per employee, self-insurance by size of company, and health maintenance organization costs compared with insured plans.

The survey found that employee health benefits cost employers an average of nearly $1,900 per employee per year, which was an increase of 7.7 percent over 1985. Costs per employee were highest in the Pacific region ($2,147), but had increased most significantly in New England (by 9.9 percent). Average annual employee costs increased with company size. Costs were highest in the utilities industry (followed, in order of importance, by diversified companies, mining/construction, and consumer products) and lowest in wholesale/retail trade. Employers with 50 percent or more of their employees under collective bargaining agreements had an average annual cost per worker of $2,255, compared with an average of $1,764 for employers with fewer than 50 percent unionized employees.

Employee contributions to the cost of health plan premiums were required by 41 percent of the companies for individual coverage and by 70 percent of the companies for family coverage. Fourteen percent of the companies required employees to pay the total costs of health coverage. Employee health plans in 91 percent of the companies required a deductible, and in 40 percent of the plans that required a deductible, the amount was $150 or more. Forty percent of the employers had built-in incentives to obtain second opinions for surgery, while 59 percent imposed penalties for not doing so. However, 74 percent of the employers with second opinion surgical programs did not know if the program had produced savings.

Forty-six percent of respondents were self-funded for employee health benefits. An additional 18 percent of the respondents used minimum-premium insurance arrangements, and 26 percent purchased experience-rated health insurance. The percent of companies that self-funded employee health benefits increased in direct proportion to company size. Only 31 percent of employers with fewer than 500 employees (the smallest size category in this survey) were self-insured. Firms in all size groups of 1,000 employees or more exceeded the self-funded average of 46 percent. Seventy-five percent of the largest firms (30,000 employees or more) were self-insured. Commercial insurers and BC/BS continued to administer benefits for most self-insured plans (49 and 30 percent, respectively), but 21 percent of the survey respondents used third party administrators for some or all of their claims, and 11 percent of the companies self-administered at least part of their plan.

Fifteen percent of responding employers offered a PPO option, which they claimed reduced total benefit plan hospital costs by an average of 11.4 percent. Fifty-four percent of all respondents offered at least one HMO option (smaller companies, fewer than 500 employees in this survey, were less likely to offer HMO options), but 68 percent of those that did, reported that HMO rates were as high or higher than their indemnity rates. Only 42 percent of the employers agreed that HMOs were effective in controlling costs.

In terms of health benefit plan design, 86 percent of the plans covered outpatient surgery, 79 percent covered home health care, and 64 percent covered hospice programs. Sixty-two percent of respondents offered retiree health plan coverage.

The survey asked two questions specifically about AIDS: how many employers were measuring the cost impact of AIDS and ARC cases on their health plans; and how many employers were modifying their health plan design (whether by expanding or limiting services was not specified) to deal with AIDS? Among all respondents, 3 percent of the employers reported measuring the cost impact of AIDS, and 2 percent indicated they were modifying their health plan designs. Percentages of employers measuring the cost impact of AIDS, by geographic region, were as follows: 5 percent in the south central and south Atlantic States; 2 percent in the mid-Atlantic and Pacific regions; and 1 percent in mountain, north central, and New England areas. Companies in the mid-Atlantic and south Atlantic regions (3 percent) were more likely to be modifying their health plans than other regions.

By industry, 11 percent of companies in communications were measuring the impact of AIDS, but none were modifying their health plans. Seven percent of employers in the education field measured cost impact, and 10 percent were modifying their health plans. Employers in the utilities, transportation, and insurance industries also were more likely than average (6 percent of companies in each industry) to measure the costs of AIDS and ARC. Companies in the 10,000 to 20,000 employee size group were most likely to measure AIDS cost impacts (10 percent), followed by companies in the 5,000 to 10,000 employee group (8 percent). There was less variation in the percentages of companies by size group that were modifying their health plans, however, with all sizes ranging from 1 to 3 percent on this question.

A 1986 Group Benefits Survey examined health, disability, death, and retirement benefits offered by 1,418 employers in 50 States (323). The companies surveyed covered more than 6 million salaried employees (about 10 percent of the U.S. workforce). This survey is the most useful of the private surveys because it is the largest, and its sample was selected to represent the location, size, and industry distributions of all U.S. employers. More small businesses were included in this sample than in the other surveys (a quarter of the sample was firms with 10 to 249 employees, and an addtional one-third of surveyed firms had 250 to 1,000 employees), including the BLS surveys, which focus on medium and large firms.

In addition, since 1974 these Group Benefits Surveys have been conducted every 2 years to provide trend data for a core group of employers. The 1986 survey, for example, presents trend data for 263 employers studied in 1982, 1984, and 1986, and included the following findings:

1. 55 percent of comprehensive health plans required employees to pay deductibles higher than $100, an increase from 9 percent in 1982;
2. the number of major medical and comprehensive health plans requiring employee contributions increased by 19 and 26 percent, respectively, since 1982;
3. 60 percent of employers self-insured their plans in 1986, compared with 40 percent in 1982.

Benefits in self-insured health plans most often were administered by insurance carriers.

In 1986, 70 percent of the employers provided comprehensive medical plans, and more than 60 percent offered an HMO/PPO option. Fifty-one percent of the employers provided medical and death benefits for retired workers, although 10 percent of employers were considering reducing those benefits.

The main focus of the 1986 survey was on employer health cost containment strategies. Health costs averaged $1,460 per employee, and represented 8 percent of the total covered payroll (all group benefits combined represented an average 16 percent of payroll). Health costs per employee were higher than average for the smallest firms (1 to 99 employees, which averaged $1,554 per employee) and for those with more than 5,000 employees (average costs, $1,522). This survey found, as did the other surveys, that employers are shifting a growing share of health care expenditures to their employees, and at the same time are taking steps to encourage the use of fewer and less costly medical services. Ninety-seven percent of employers applied at least one approach to health cost containment (e.g., outpatient treatment, preadmission testing), and more than a third applied 10 or more specific methods. Eighty-eight percent of the companies reported achieving a reduction in plan costs (averaging 13 percent) since implementing cost controls.

The most commonly used cost containment methods in 1982 and 1986 (for the core group of 263 employers) were use of ambulatory surgical facilities, preadmission testing, extended care facilities, and second opinion surgery programs. The greatest increases in use of specific methods from 1982 to 1986 were in home health care (offered by 7 percent of plans in 1982, 75 percent in 1986) and hospice care (an increase from 15 percent to 55 percent). In 1986, 26 percent of all 1,418 plans offered employee assistance programs; 67 percent covered alcohol abuse treatment; 63 percent covered drug abuse treatment; and 6 percent offered health risk screening.

There was also a clear trend toward self-insurance of employee health benefits. The breakdown of group health plan funding and administration was as follows: self-funded, carrier administered, 27 percent; minimum premium, carrier administered, 22 percent; fully-insured, carrier administered, 21 percent; self-funded, self-administered, 8 percent; and other, 2 percent. The percent of employee health plans provided through commercial insurance carriers declined from 57 percent in 1978, to 42 percent in 1982, 33 percent in 1984, and 22 percent in 1986. Over the same period, self-insured medical plans increased from 23 percent to 49 percent of all plans.

In the view of staff involved with the surveys, most businesses have not yet taken action to monitor employees with AIDS because most have not had experience with such employees. At this point, most intend to treat AIDS and ARC in the same manner that other catastrophic conditions are treated; that is, in most firms, such services will be covered by the group health plan. The question that has not yet been answered, is the effect AIDS may have on the costs of catastrophic insurance and on the costs of stop-loss policies that are especially important to self-insured firms (194).

A final source of information is the Health Care Financing Administration (HCFA), which surveys employers to develop data for its estimates of national health care expenditures. One of its surveys focuses on independent health plans, which are either fully or partially self-insured, or operate on a prepaid basis. The most recent analysis of independent health plans, surveyed in 1984 and reported in 1986, found that 8 percent of all employment-related health plans were self-insured, representing about 175,000 self-insured plans and covering more than 50 percent of all employees with health benefits. Among employers that self-insured, 23 percent self-administered their plans and the remaining 77 percent used a commercial carrier, BC/BS plan, or third party administrator (TPA) (178).

The striking difference between the 8 percent prevalence of self-insurance found in the HCFA survey and estimates in the area of 50 percent reported by the Bureau of Labor Statistics and private consulting firm surveys can be explained by the size of the firms included in the different surveys. The HCFA survey sample represented the more than 90 percent of employers that have fewer than 100 employees and therefore rarely self-insure; in the HCFA study, only 6 percent of employers with fewer than 100 employees self-insured (178). HCFA in fact compared its findings with those of other surveys and found that the findings were consistent, because the other surveys were weighted toward the larger companies. Companies included in the BLS surveys, for example, must have at least 100 or 250 employees, depending on the industry. The HCFA survey found that in 1984, one-third of employers with more than 100 employees, more than one-half of employers with 250 and more employees, threefourths of employers with 1,000 or more employees, and four-fifths of those with 5,000 or more employees were partially or fully self-insured (178).

In the HCFA survey, private businesses and unions were more likely to self-insure than other organizations, such as religious organizations, governmental units, and post-secondary schools. Seventy-four percent of all businesses with 1,000 employees or more, and 83 percent of unions with 1,000 or more employees self-insured their health benefits. All organizations that self-insured were more likely to self-insure hospital and medical benefits than dental or vision care.

In 1984, 23 percent of self-insured organizations also self-administered their benefit plans, while 51 percent used a TPA, 6 percent contracted with BC/BS, and 20 percent used the administrative services of a commercial insurer. TPAs were the preferred administrator for smaller self-insured firms, and small business is the area where the greatest future growth in self-insurance is expected. TPA administration may be less expensive, according to a study noted by HCFA, which found that TPAs spent about $1.75 per month per employee on claims processing and $1.75 per month on corporate overhead, while commercial carriers spent $4.75 per month on claims processing and $1.25 per month on corporate overhead. The HCFA survey also found that businesses (24 percent) and unions (35 percent) were more likely to self-administer their benefits than other types of organizations.

The likelihood that an employer-provided health plan will offer a HMO/PPO option increased with employer size, ranging form 3 percent of plans for fewer than 100 employees offering the option to 87 percent of plans of 50,000 and more. HMO/PPO options were offered by 4 percent of all organizations (including 4 percent of businesses), but by 15 percent of unions, 14 percent of religious organizations, 35 percent of post-secondary schools, and 10 percent of governmental units.

HCFA found that preliminary data and anecdotal evidence suggested that employees covered by self-insured health plans have less generous medical, surgical, and other benefits (178). The HCFA Division of National Cost Estimates plans further work to study the extent to which the benefits provided by self-insured health plans differ from those of private insurance plans, which must comply with State-mandated benefits requirements (177).

The HCFA report added that the Employee Benefits Research Institute "found that employer contributions in 1984 for health care—which includes premiums paid to insurers and medical claims payments by self-insured employer — equaled 2.57 percent of the gross national product, down from 2.63 percent in 1983," although the decline might be attributable to other factors.

## Self-Insured Employee Health Benefit Plans

Self-insured employers assume full responsibility for their employees' actual health care expenses, or limit their liability with "stop-loss" insurance against high-cost cases. Self-insurance has other implications for AIDS patients; because self-insured plans are exempt from State insurance regulations, including State mandated benefits, they may be able to selectively limit plan coverage, for example, excluding services for AIDS patients. State mandated benefit laws are intended to protect workers from arbitrary benefits exclusions in their employer-provided health plans and to encourage more comprehensive health coverage. Some employers already have tried to fire employees with AIDS or to exclude AIDS coverage from their insurance policies. Most employers, however, have stated that AIDS would be treated no differently from other diseases, while other employers have not determined what their policies toward AIDS employees will be.

The rapid growth of self-insurance does raise special concerns related to medical testing in the workplace. Medical conditions such as AIDS and ARC could affect self-insured employers differently than employers with conventional insurance, and self-insured employers have different means of responding to the problems of high-cost employee health benefit claims.

While turning to self-funding, however, the majority of employers continue to contract with commercial carriers and BC/BS plans for claims processing and administrative services. A large share of self-insured employers also purchase stop-loss insurance to limit the amount of their liability for medical claims. Administrative services contracts have expanded from 5 percent of private insurance before 1975 to 25 percent by 1980 and nearly 50 percent by 1984, and 1983 data indicate that 60 percent of the business of the 10 largest commercial carriers came primarily from administrative services and minimum premium plan arrangements (83).

Growth of self-insurance, and especially its rapid advances since about 1980, can be attributed largely to two factors: 1) the continued high health care cost inflation that has increased health insurance premiums by as much as 30 percent per year; and 2) the exemption of self-insured plans from State insurance regulation (including State insurance premium taxes) and State mandated health benefits (159,251). The extent of self-funding among businesses of various sizes and industries as determined by several of the private employee health benefit plan surveys (described above) are in the range of 50 percent, with larger firms much more likely to self-insure than smaller companies (fewer than 100 to 250 employees). For example, in one survey, 70 percent of employers with 10,000 to 20,000 employees self-insured (151). Other estimates of the percent of companies that self-fund fall between 50 and 60 percent, with expectations that by the 1990s, the value of self-insured plans will exceed the combined value of all commercial plans and will approximate that of the combined Blue Cross plans (251).

As a result of this trend to self-insurance, new types of service companies are emerging as competitors of traditional insurers for the business of administering employer plans. For example, one type of company may specialize in reinsurance, the stop-loss coverage that many self-insured employers need. The TPA industry has grown along with self-insurance to provide claims processing services. In 1984, TPAs served about 6,700 self-insured employers with more than 5 million employees (83). TPAs have become such an important factor in self-insured plan administration that large insurance companies are beginning to buy them up. Other firms are specializing in automated data processing services.

Small businesses, in particular, are likely to turn to TPAs when setting up self-insurance health benefit plans. Perhaps half of all businesses with fewer than 500 employees rely on TPAs for benefits administration (172).

The range of services provided by a TPA can be negotiated according to employer needs, but most employer-TPA contracts provide for medical claims processing; cost control programs, including utilization and charges review; selection of appropriate stop-loss insurance; monitoring of Federal and State regulations, and other administrative functions, such as data processing and reporting. TPAs may also work directly with the employer to design the benefits package.

The term "third party administrator" was originally used in the Taft-Hartley legislation of 1947 to designate an entity that is neither union nor management, but that administers joint labor-management welfare and pension funds. There were relatively few TPAs performing this function until the late 1970s, when administrative services for self-insured benefit plans began to develop as a market. There are approximately 1,500 TPA firms operating today, although relatively few of them are qualified, full-service TPAs (172).

The exemption of self-insured health benefit plans from State insurance regulations and mandated benefits as a consequence of judicial interpretation of the ERISA (Employee Retirement and Income Security Law) law of 1974 does not mean that self-insured plans are entirely unregulated. Exemption from State regulation means that self-insured plans are subjected to Federal regulation through the Department of Labor and the Internal Revenue Service. Federal regulation to date, however, has been slight, and for that reason, the need to amend ERISA to eliminate the self-insured plan exemption (and to make them subject to contributions to State high-risk insurance pools) has been debated for several years. TPAs that administer self-insured employee benefit plans are regulated in 23 States in much the same way that insurance companies are regulated, with emphasis on ensuring plan solvency (in these States, TPAs must be bonded and pass financial stability requirements) (54,172).

In 1984, ERISA was amended to allow States to regulate multiple employer trusts (METs), but Congress has not taken action to further amend ERISA to clarify or eliminate the distinction between insured and self-insured health plans. In the 1985 COBRA legislation that required employers to provide continuation coverage for laid-off and terminated employees, however, self-insured health plans were required to participate along with other insured plans.

A company may take a variety of approaches in self-funding its employee health benefits. While assuming liability for employee health expenses, a company may contract with a commercial insurer for an administrative services only (ASO) contract, including claims processing and overall administration. Or a company may contract on a similar basis with a TPA. A company may also decide to both self-fund and self-administer its plan, but this option is selected primarily by very large corporations. The most common approach is for the company to establish a health benefits fund and then take bids for the desired administrative services. The company may or may not purchase stop-loss insurance for protection against catastrophic risk, but the smaller the company, the more necessary stop-loss insurance will be; without stop-loss insurance, size would limit the companies that could exercise the self-insurance option.

The choice of using a minimum premium plan depends on where the employer does business, because some States consider these plans as insurance, and regulate them. Minimum premium plans provide for employers and insurers to share the cost risk, with a limit on employer liability, and with payments to the insurers for administrative costs and risk sharing much like insurance premiums (251).

The advantages to the employer of self-funding include the following:

- exemption from State insurance premium taxes (usually 2 percent of premiums);
- no payment for carrier overhead, including marketing, sales, and profit (administrative costs of a self-insured plan are lower than the retention charges of an insured plan);
- ability to earn interest on the health benefit fund and regulate cash flow to the employer's advantage (the employer may fund the paid claims on an ongoing basis rather than paying a year's insurance premium in advance);
- savings may accrue from employer management and utilization review of medical claims, and self-insured employers only negotiate administrative costs with their carriers or TPAs, not premium rates and claim projections;
- health plan savings due to exemption from compliance with State mandated benefits (most State insurance laws and regulations apply to insurance contracts and not to self-insured benefit plans); and
- exemption from contributions to State high-risk pools, where they exist.

Disadvantages include:

- the self-insuring employer may be exposed to greater financial risk in the form of aggregate claims in a bad year or a few catastrophic cases;
- by contracting for administrative services only, the employer gets less expertise than he would get as a fully insured client, or would require more staff with specialized health benefits expertise; and
- the employer loses the insurance company as a buffer between the employer and employees in disagreements over claims coverage (327).

The most significant of the employer's disadvantages in self-funding is the assumption of risk, which is why stop-loss insurance is an attractive added protection for many self-insured firms. Stop-loss insurance is [illegible] often purchased for medium-sized health plans [illegible] 200 to 1,000 employees (327). Among companies with 500 or fewer employees, 25 percent self-insure with stop-loss coverage, while only 6 percent assumed full risk (151). Thirty-five percent of companies with 500 to 1,000 employees self-insure with stop-loss, and 7 percent went without stop-loss coverage; while 41 percent of companies with 1,000 to 2,500 employees self-insure with stop-loss, and 15 percent go without it (99).

The two types of stop-loss insurance are: 1) specific stop-loss, which reimburses the employer for claims for any individual employee that exceed a specified amount; and 2) aggregate stop-loss insurance, which reimburses the policyholder if total claims paid for all employees exceed a predetermined deductible, for example, 125 percent of expected claims. Both forms of stop-loss are written with high deductibles to keep the stop-loss premium relatively low. The cost of stop-loss insurance can vary substantially from one policy to another, depending on such factors as plan design (level of deductible and maximum benefit) and competition among stop-loss insurers, who may evaluate risk differently based on medical costs by geographic area, inflation factors, the range of benefits in the employer's primary plan, the employees' age distribution, and the employer's recent experience (327).

## Employment "Wellness" Programs

In a 1985 telephone survey of 1,358 worksites with 50 employees or more (306), 65 percent of worksites had at least one health promotion activity. Thirty-six percent had smoking control activities; 27 percent, stress management programs; 22 percent, physical fitness activities; 17 percent, nutrition activities; and 15 percent, weight control activities (box 3-B).

Such employment-based "wellness" programs often include health risk appraisals (HRAs) in efforts to reduce the costs associated with preventable chronic illnesses (109). Over 200 organizations now offer HRAs to employees, patients of medical care organizations, students, and to the general public. An HRA is a health promotion technique that involves three procedures:

1. measurement of risk factors of the individual through the use of a personal inventory of health habits and, in many cases, a number of clinical measurements (e.g., blood pressure, serum cholesterol, height, weight, etc.);
2. estimation of the individual's expected risk of death from specific causes or diseases based on his or her personal risk factors, epidemiologic data, and national mortality statistics using actuarial techniques; and
3. presentation of these risk estimates to the individual, with a discussion of how selected changes in personal lifestyle and health habits could possible affect health risks (128).

For example, one company (70) is pilot-testing a program in which information from a health history questionnaire and a number of predictive tests are used to tailor health risk information to individuals. As part of the pilot study, the company is offering voluntary, confidential testing to members of an employee group. Predictive tests are being validated for a number of disorders, including cardiovascular disease, diabetes, cancer of the breast and colon/rectum, and periodontitis. When the program is implemented, information from the computer-analyzed family and personal medical history will be used to select appropriate tests for each employee. Information from the tests and the health history will be used to provide individualized health education to participants. This company has expressed an interest in future use of genetic and biologic markers for chronic disease (e.g., genetic markers for heart disease) but will limit testing to diseases in which some form of primary or secondary intervention is possible.

Criticisms of HRA techniques include:

- information is provided regarding risk of death but not risk of disease;
- epidemiologic bases of risk estimation do not exist for groups other than white, primarily middle-class individuals;
- self-reported behaviors and risk factors used in the assessments may not be reliable; and
- there is insufficient evidence that changes in specific risk factors actually reduce the risks of developing certain diseases or of death from specific causes (300).

There is, however, evidence that self-reported risk factors and behaviors are predictive of an individual's future health care costs. One actuarial firm has related health risk and health behavior information (i.e., exercise, weight, smoking, hypertension, alcohol use, cholesterol level, and seat belt use) collected from employees participating in a health promotion program to their medical claims costs and hospital inpatient days. Age and sex were controlled for in the analyses, and cost data were adjusted for geographic variation. In many cases, significant differences were noted

**Box 3-B.—National Survey of Worksite Health Promotion Programs, 1985**

In 1985, the U.S. Department of Health and Human Services (DHHS) conducted a National Survey of Worksite Health Promotion Activities: 1) to determine the nature and extent of worksite health promotion activities in worksites of 50 or more employees; 2) to determine what employers perceive as the direct and indirect benefits of their efforts to prevent disease and promote employee health; and 3) to monitor progress toward the worksite health promotion goals set forth in DHHS's 1990 Health Objectives for the Nation.

DHHS concluded that: 1) many employers have recognized the benefits of instituting health promotion activities for their employees; 2) employers also acknowledged that these activities also enhanced company image and improved employee morale and performance; and 3) few negative effects resulted from instituting these activities.

Major findings of the survey included:

- Over 85 percent of surveyed worksites with health promotion activities indicated that all employees at the site were eligible to participate. Approximately 30 percent also made the activities available to dependents, and the same percent offered activities to retirees;
- 65 percent of worksites surveyed had at least one health promotion activity; smaller worksites were less likely to have health promotion activities;
- 36 percent of all worksites surveyed had smoking control activities;
- 27 percent of all worksites surveyed offered stress management activities;
- 22 percent of all worksites surveyed had some form of physical fitness or exercise activity;
- Fewer of the worksites surveyed offered activities related to nutrition (17 percent) or weight control (15 percent), even though 43 percent of these worksites had a cafeteria with an onsite cafeteria manager.
- An overwhelming majority of respondents indicated that benefits of their activities outweighed or equaled the costs. Only a small percentage said that costs outweighed benefits or had other negative comments; and
- Over 81 percent of respondents said they were extremely or moderately concerned with health care cost management.

SOURCE: U.S. Department of Health and Human Services, Public Health Service, Office of Disease Prevention and Health Promotion, *National Survey of Worksite Health Promotion Activities* (Silver Spring, MD: ODPHP, 1987).

between high- and low-risk employees' medical costs. For example, those reporting systolic blood pressure of 159 mmHg or higher and a diastolic pressure of 94 mmHg or higher were 68 percent more likely to have annual claims of more than $5,000 than those reporting normal blood pressure. (High blood pressure is defined as a systolic pressure greater than or equal to 140 mmHg and/or a diastolic pressure greater than or equal to 90 mmHg.) The largest difference in hospital utilization was associated with seat belt use; high-risk employees in this category used 54 percent more hospital days per thousand than those regularly using seat belts (199).

## Conclusions on Employer-Provided Health Benefit Plans

The majority of employers provide comprehensive health benefits for their employees, often (about half of the plans) at no cost to the employee. The range of services covered under group health plans has grown to include more outpatient and employee support services. These additions have been made at least in part to encourage employees to use outpatient services, which are less costly than similar services provided on an inpatient basis.

The trend to shift part of the costs of employee health benefits to employees has been strong since about 1980. One or more cost containment methods have been incorporated into almost all health plans. One of the most important steps employers have taken for cost containment is the decision to switch from commercial or BC/BS insurance to self-insurance, often with stop-loss coverage against catastrophic claims. The share of commercial carriers in the employee health benefits market has declined substantially, even though insurance companies continue to administer the majority of self-insured plans. The generosity of employee health benefits and the preferred funding-administrative approach vary somewhat with company location, size, and industrial sector. Company size (i.e., number of employees), however, is a particularly important factor, and it is emphasized by the predominance of small businesses in the relatively volatile service and retail sectors of the economy.

"Wellness" programs and health risk appraisals are also becoming relatively common at the worksite. While there is as yet insufficient evidence that changes in specific risk factors actually reduce the risk of developing certain diseases or of death from specific causes, there is evidence that self-reported risk factors and behaviors are predictive of an individual's future health care costs. Employers who provide health care coverage to their employees are concerned with managing their health care costs, and at least some of the risk factors (e.g., high blood pressure, seat belt use) leading to higher health care costs are preventable.

## Chapter 4

# Tests To Diagnose or Predict Disease

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## Chapter 4

# Tests To Diagnose or Predict Disease

## INTRODUCTION

Medical tests that provide information on the present or future development of disease may be useful adjuncts to the health insurance underwriting process. In general, two types of tests can be distinguished—diagnostic and predictive tests. Diagnostic tests are used to identify the cause of abnormal physical signs or symptoms. In contrast, predictive tests are generally applied to asymptomatic individuals and are used to provide information regarding the future occurrence of disease.

Diagnostic and predictive tests may be used in a medical screening program to identify latent disease or disease predisposition (i.e., it may be diagnostic or predictive in intent). In general, a screening program involves administering a screening test to an asymptomatic population to sort out apparently well persons who probably have disease (or who have an increased likelihood to develop a disease) from those who probably do not have disease (or probably will not develop disease) (figure 4-1). More definitive tests are then administered to those identified by the screening test as being at risk. Some screening programs employ "non-medical" tests to detect behaviors associated with disability or disease. Examples include tests for drug or alcohol use and nicotine tests to identify current smokers.

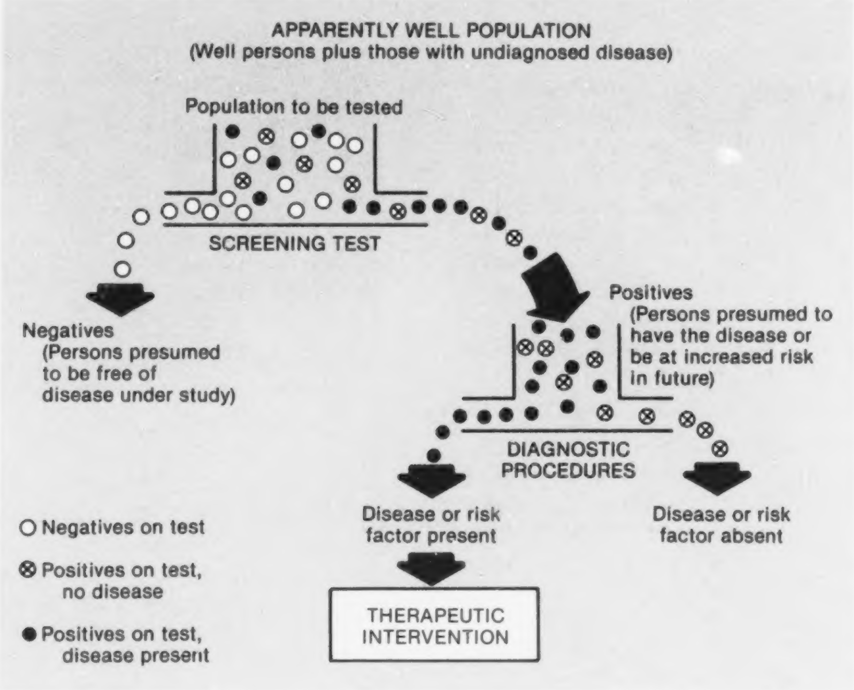
According to one insurance company's position paper on the use of genetic tests and tests for disease predisposition, several conditions should be met before a medical test is adopted by insurers (45).

- The test must supply information in addition to information otherwise available from other sources (e.g., from the medical history questionnaire).
- The disease tested for must have serious morbidity and/or mortality implications.
- The disease must be common enough to ensure that the test is predictive and that the cost can be justified.
- The test must be predictive of disease (or absence of disease) and reliable.
- The test must be understood, accepted, and used by the medical profession.
- Laboratories must be able to readily perform the test.
- The test must be affordable and able to provide results quickly.
- The test must be risk-free.

Public health officials, who are principally concerned with establishing screening programs to prevent disease or ameliorate the consequences of disease, consider additional criteria. They are especially concerned with: 1) whether there is a recognizable latent or early symptomatic stage during which therapeutic interventions may be successful, 2) whether there is an accepted treatment for patients with recognized disease, and 3) whether facilities for diagnosis and treatment are available. Clearly, insurers are mindful of these considerations as well, as they would have little interest in testing for a condition that could be inexpensively and effectively treated. Insurers also consider disease latency; there would be little value in a test that predicted the occurrence of a disease with a late onset (e.g., age 65 or older). Instead, insurers are more interested in tests for diseases that afflict younger persons and that have no effective treatment or are very costly to treat.

For persons applying for individual or small group health coverage, insurers often refuse to insure or offer insurance on a substandard basis to those with evidence of significant disease, including heart disease (e.g., history of angina pectoris, arteriosclerosis) and insulin-dependent diabetes. If predictive tests are developed for diseases that are currently the basis of exclusion or substandard coverage, how likely are they to be used to test healthy applicants? The answer, in part, will depend on the availability of preventive interventions. If interventions are unavailable, predictive tests may only be of interest to insurers if they

Figure 4-1.—Flow Diagram for a Mass Screening Test


APPARENTLY WELL POPULATION
(Well persons plus those with undiagnosed disease)
Population to be tested
SCREENING TEST
Negatives
(Persons presumed to be free of disease under study)
Positives
(Persons presumed to have the disease or be at increased risk in future)
DIAGNOSTIC PROCEDURES
Disease or risk factor present
Disease or risk factor absent
THERAPEUTIC INTERVENTION
○ Negatives on test
⊗ Positives on test, no disease
● Positives on test, disease present

SOURCE: J.S. Mausher and A.K. Bahn, *Epidemiology: An Introductory Text* (Philadelphia, PA: W.B. Saunders Co., 1974).

are very accurate. If inaccurate, many applicants not destined to become ill would be excluded or subjected to expensive follow-up testing.

Predictive testing may also be used to establish preventive health plans. For example, the availability of such tests and concerns regarding health cost containment may foster the establishment of employee "wellness" programs. If a predictive test for heart disease is developed and an effective intervention is available, an employee may be tested and encouraged to comply with preventive measures.

At the present time, tests conducted on applicants at the request of commercial health insurers are largely limited to biochemical profiles, tests for Human Immunodeficiency Virus (HIV) infection, and specific drug tests.

## TESTS CURRENTLY USED BY HEALTH INSURERS

Most of the blood tests used by health insurers are those biochemical profiles used frequently by clinicians. Such profiles are generally a battery of twelve or more tests that are performed on each blood sample as part of a large-volume, automated-testing program. Although it is recommended that medical tests be administered on the basis of clinical findings, the ease with which a large number of tests can be conducted at relatively low cost has led in part to the routine use of biochemical profiles. For example, biochemical profiles have been used to screen asymptomatic patients in ambulatory clinics and as part of routine hospital preadmission workups.

Table 1-1 in chapter 1 identifies the blood and urine tests conducted at a major laboratory that serves commercial insurers and the conditions the tests may detect. The sensitivity of these tests, or the ability of the tests to correctly identify those with the corresponding conditions, depends on the particular tests. For example, the total serum protein level is not very sensitive for any of the conditions with which it is associated. In contrast, increased levels of high glucose (sugar) are almost always detected in those with diabetes mellitus.

An abnormal result is usually defined by setting a cutoff value, beyond which values are deemed abnormally high (or low). In general, a result that deviates markedly from the mean value for a given population is more predictive of disease than one that deviates only slightly. However, when the cutoff value is established by using certain statistical criteria (such as the mean value for the test in a population of presumably nondiseased persons, plus or minus two standard deviations), as the number of tests administered increases, the likelihood that an individual will, by chance, have at least one abnormal test result also increases (table 4-1).

If the test is positive, how likely is it that the person tested has the condition in question; and if the test is negative, how likely is it that the person is disease-free? Stated another way, what is the test's predictive value, or the probability that a positive test correctly identifies the presence or the future development of the indicated condition or disease?

**Table 4-1.—The Probability That a Healthy Person Will Have at Least One Abnormal Result in a Biochemical Profile**

| Number of tests | Probability that at least one test will be abnormal (percent) |
|---|---|
| 1 | 5% |
| 6 | 26 |
| 12 | 46 |
| 20 | 64 |
| 100 | 99 |

SOURCE: Adapted from R.D. Cebul, and J.R. Beck, "Biochemical Profiles: Applications in Ambulatory Screening and Preadmission Testing of Adults," *Common Diagnostic Tests: Use and Interpretation*, H.C. Sox, Jr. (ed.) (Philadelphia, PA: American College of Physicians, 1987).

In one study of 8,651 patients who were tested as part of a multiphasic health checkup, use of a biochemical profile consisting of 8 tests resulted in 26 percent of patients having at least 1 test abnormality. In the case of serum glucose, although 6 percent of adults had elevated levels, less than 30 percent of them had elevations when the test was repeated. Furthermore, disease was confirmed in less than 17 percent of those with repeatedly abnormal test results (96). Similarly, approximately 3 to 4 percent of asymptomatic adults will have abnormal serum creatinine and blood urea nitrogen levels, but few will have actual kidney disease (44).

The predictive values of biochemical profile test results among patients about to be admitted to the hospital are comparable to those cited above. Experience from such programs indicates that 40 percent of such patients will have abnormal tests but that these results will lead to new diagnoses in only approximately 4 to 10 percent of patients (44).

The Blue Cross and Blue Shield Association has published guidelines on the use of biochemical profiles in both ambulatory settings and hospital preadmission testing programs (these guidelines were written with the cooperation of the American College of Physicians, the American College of Radiology, and the American College of Surgeons). The guidelines state that biochemical profiles are not routinely indicated for screening asymptomatic adults or those without risk factors, nor are they indicated prior to elective admission to the hospital (207). However, the guidelines state that selected components of biochemical profiles may be indicated for screening asymptomatic adults; specifically, serum glucose (to identify diabetes mellitus), serum cholesterol (to identify hypercholesterolemia), and serum creatinine, with or without blood urea nitrogen (BUN) (to identify kidney dysfunction).

Insurers usually selectively test those with medical histories indicative of disease or risk of disease. If a relatively high-risk group of individuals is tested, the predictive value of the tests would be expected to be higher than in unselected testing. There is evidence that insurance applicants are being selectively tested. For example, according to 1986 insurance testing data from the Home Office Reference Laboratory, Inc. (HORL) which conducts tests for more than 80 percent of life and health insurance companies in the United States and Canada, 15 percent of applicants between the ages of 20 to 59 who were tested had abnormal blood glucose levels (246). In contrast, in a study performed by others of unselected adult patients tested as part of a multiphasic health checkup, only 6 percent had abnormal blood glucose levels (96).

While controversy surrounds the use of tests for HIV infection by insurers, insurers are selectively testing life and health insurance applicants when permitted to do so. HORL, the lab that does most of the testing for the insurance industry, uses state-of-the-art technology in the operation of a high-volume, largely automated laboratory. When applicant blood specimens are sent from locales in which HIV antibody testing is permitted, HORL uses the recommended two-stage testing protocol. First, an enzyme-linked immunosorbent assay (ELISA) is used to test serum or plasma for the presence of antibodies to HIV. These tests are very sensitive and therefore detect nearly all of those who have produced antibodies to HIV. However, they falsely identify as positive some that have not been infected. To more accurately identify noninfected individuals, a confirmatory test (sometimes called a supplemental test), the Western blot, is used. In 1986, 128,129 HIV antibody tests were performed by HORL (for a total of 213,193 life or health insurance applicants). Of those tested, 385 (0.3 percent) were Western blot-confirmed as positive. Among the 13,759 applicants in the 20-to-29 year-old group, 8,312 were tested for the presence of antibodies to HIV and of these, 85 (1 percent) were confirmed as HIV infected (246). Table 4-2 summarizes HORL testing for HIV antibodies by age groups for 1986.

**Table 4-2.—Age-Specific HORL HIV Antibody Test Statistics for 1986**

| Age group | Number of tests | Number of positive tests | Percent of positive tests |
|---|---|---|---|
| 1-19 . . . . . . . . . | 395 | 1 | 0.25% |
| 20-29 . . . . . . . . . | 8,312 | 85 | 1.02 |
| 30-39 . . . . . . . . . | 35,417 | 173 | 0.49 |
| 40-49 . . . . . . . . . | 38,831 | 75 | 0.19 |
| 50-59 . . . . . . . . . | 31,226 | 46 | 0.15 |
| 60-up . . . . . . . . . | 13,948 | 5 | 0.04 |
| Total . . . . . . . | 128,129 | 385 | 0.30% |

SOURCE: Home Office Reference Laboratory, Inc. (HORL), unpublished data, Shawnee Mission, KS, 1986.

When HIV antibody testing is prohibited (e.g., in California), insurers test applicants by using a surrogate test, the T-lymphocyte (or T-cell helper-suppressor ratio) test. This test of immune function is much less accurate than the antibody test in identifying HIV-infected individuals. According to a study conducted by HORL, the T-cell test failed to detect 18 percent of 234 specimens that had tested positive for HIV antibodies (113). (Furthermore, a study of 65 asymptomatic HIV antibody-positive blood donors done elsewhere revealed that none had abnormal T4/T8 cell ratios (161).) To determine the predictive value of the T4/T8 ratio, HORL tested 209 specimens with T4/T8 ratios less than 1.0 for HIV antibodies. Only 8 percent of specimens were confirmed positive for antibodies. The predictive value increased somewhat as the T4/T8 ratio decreased (113).

The T-cell test may be abnormal when there is no HIV infection, because it is a general test of immune function. HORL's 1986 testing data indicate that 1 percent of the 25,611 T-cell tests conducted (for a total of 213,193 life and health insurance applicants) were positive. Table 4-3 summarizes HORL T-cell testing by age groups for 1986. Note the relatively high percent of positive tests in the older age groups, who would be least expected to be HIV antibody-positive.

**Table 4-3.—Age-Specific HORL T-cell Test Statistics for 1986**

| Age group | Number of tests | Number of positive tests | Percent of positive tests |
|---|---|---|---|
| 1-19 . . . . . . . . . | 48 | 0 | 0.00% |
| 20-29 . . . . . . . . . | 1,379 | 24 | 1.74 |
| 30-39 . . . . . . . . . | 6,377 | 86 | 1.35 |
| 40-49 . . . . . . . . . | 8,504 | 76 | 0.89 |
| 50-59 . . . . . . . . . | 6,291 | 74 | 1.17 |
| 60-up . . . . . . . . . | 3,012 | 30 | 1.00 |
| Total . . . . . . . | 25,611 | 290 | 1.13% |

SOURCE: Home Office Reference Laboratory, Inc. (HORL), unpublished data, Shawnee Mission, KS, 1986.

While some insurers are prohibited from performing HIV antibody tests they are not explicitly prohibited from using HIV antigen tests. Several commercial products are available for research use (at present, none are FDA-approved for diagnostic purposes). Such tests have been useful in detecting early infections at a time before HIV antibodies are detectable. However, once antibodies are produced, the antigen test may be negative. Therefore, such a test would not be as useful as the antibody tests, and there is no evidence that insurers are using such tests.

# TESTS FOR HIV

## The ELISA and Competitive EIA Screening Tests

Several manufacturers have been licensed by FDA to market HIV screening test kits. Most of the test kits are enzyme immunoassays (EIA) that identify IgG antibodies (one of several classes of antibodies) made in response to HIV infection. The EIA tests (ELISA tests are a type of EIA) were initially designed to screen blood products, and according to data submitted to FDA by the manufacturers, most kits can detect virtually all individuals with AIDS (table 4-4). However, the tests will not identify recently infected individuals who have not yet produced antibodies to the virus. Furthermore, during the early stages of infection, some individuals (e.g., newborns) make antibodies (IgM) that are not detected by the available tests. However, almost all infected individuals will test positive 1 to 4 months after infection (60).

**Table 4-4.—Commercially Available (U.S.) HIV Screening Test Kits[a]**

| Manufacturer and test name | Sensitivity[b] | Specificity[c] |
|---|---|---|
| Abbott Laboratories | | |
| Abbott HTLV III EIA | 100% | 99.85% |
| Cellular Products, Inc. | | |
| Retro-Tek™ HIV ELISA | 100 | 99.85 |
| E.I. du Pont de Nemours & Co., Inc. | | |
| Du Pont HTLV-III ELISA | 99.30 | 99.70 |
| Electro-Nucleonics, Inc. | | |
| VIRGO™ HTLV-III ELISA | 100 | 99.68 |
| Genetic Systems | | |
| Genetic System LAV EIA™ | 100 | 99.80 |
| Organon Teknika, Corp. | | |
| Bio-EnzaBead™ HTLV-III ELISA | 100 | 99.97 |
| Ortho Diagnostics Systems, Inc. | | |
| ORTHO™ HTLV-III ELISA | 99.30 | 99.70 |

[a] Available as of early 1988. Several other HIV screening test kits will be available pending FDA approval (e.g., Hoffman-La Roche, Cambridge Bioscience).

[b] Sensitivity is computed as percentage of AIDS patients testing positive assuming 100% prevalence of HIV antibody in AIDS patients.

[c] Specificity is computed as percentage of random blood donors testing negative assuming zero prevalence of HIV antibody in random blood and plasma donors.

SOURCE: Office of Technology Assessment, 1988.

False-positive tests may occur, because the tests use disrupted whole-virus preparations derived from cell cultures as the antigen (viral components capable of eliciting an antibody response). Although made from purified virus, they are contaminated with cellular matter that can produce false-positive results. The cutoff levels above which a test will be interpreted as positive are set low in order to detect as many positive specimens as possible, but this also increases the chances that a specimen labeled as positive at these low levels might in fact be negative. Therefore, a specimen is not reported as positive until appropriate follow-up tests are conducted. This includes a repeat of the initially positive screening test. In fact, the repeated ELISA is done in duplicate. Only if one of the two repeat tests is positive will the serum specimen be reported as ELISA positive (or repeatedly reactive), and a confirmatory test subsequently performed. The problem of false positives attributable to contamination will be reduced when "second generation" test kits become commercially available. Instead of disrupted whole virus, these kits will use synthetic viral antigens made by using recombinant DNA techniques, thereby avoiding the problem of contamination.

## Confirmatory Tests for HIV Antibodies: The Western Blot

To confirm a positive ELISA screening test, a technique called the Western blot is used. Here, purified HIV antigens are separated electrophoretically on a gel and then blotted onto special paper. A sample of blood is applied to the paper, and, if antibodies are present, they will bind to the viral antigens and appear as distinctive bands on the blot. The location of each band indicates reaction with a specific viral protein. There are three types of HIV proteins: 1) proteins that provide the virus's internal, or "core" structure; 2) proteins that provide the external or "envelope" structure; and 3) proteins that are the enzymes (for example, reverse transcriptase) that the AIDS virus uses to regulate interactions with its host cell. The core proteins include p24/25 and p55, which are shorthand designations for proteins with molecular weights in the thousands (or "kilodaltons"). Thus, p24/25 refers to a protein with a molecular weight of 24 or 25 thousand. The envelope proteins are gp41, gp110/120, and gp160, where "gp" stands for "glycoprotein" (envelope proteins have non-protein elements—glycogen—incorporated in them), and p17/18 (previously thought to be a core protein). The regulatory enzyme proteins are p31/32, p51/53, and p65/66.

Early in the AIDS epidemic a Western blot was interpreted as positive even when antibodies to only one of the proteins (the core protein, p24/25) of the AIDS virus was present, but it soon became evident that the blood of noninfected persons could contain similar antibodies. Reactivity to core antigens exclusively may represent infection with another retrovirus (e.g., HTLV-1, which may cause a particular type of leukemia) or reactions with other substances. In such cases, a second confirmatory test is conducted in 4 to 6 months, by which time the subject should have produced antibodies to other antigens if HIV infection is indeed present.

The Western blot is visually interpreted, and a weakly reactive band may be read as positive or negative, depending on the technician. Most laboratories limit positive readings to those blots that have reactions with at least two bands, at least one of which must be an envelope antigen. A 1986 National Institutes of Health Consensus Development Conference concluded that the presence of antibodies to two HIV proteins, p24/25 (a core protein) plus gp41 (an envelope protein), constituted an "unequivocally positive" Western blot (305). However, this conclusion is under dispute, and different laboratories currently have different standards. For example, at the beginning of 1988, the American Red Cross required antibodies to at least one protein from each of the three types to be present before donors are notified that they have tested positive (85). (The Red Cross nevertheless discards all repeatedly positive ELISA blood donations.) The only commercially licensed Western blot test as of early 1988 (Biotech/duPont HIV Western Blot, Biotech Research Laboratories, Inc.) is interpreted as positive when antibodies to p24/25 (a core protein), p31/32 (a regulatory enzyme protein), and either gp41 or gp120 (both envelope proteins) are present (72). The Department of Defense (35) has adopted the definition established by the Association of State and Territorial Health Officers (ASTHO) (positive if any two of p24/25, gp41, or gp110/120-gp160 bands are present) (104). Given the subjective nature of Western blot interpretation and variations in the definition of a positive result, the establishment of a national standard for Western blot interpretation has been recommended (196).

## Other Confirmatory Tests for HIV Antibodies

When Western blot confirmatory tests are equivocal, the radioimmunoprecipitation assay (RIPA), a research procedure, may be used. However, it is expensive, uses radioisotopes, and requires considerable technical expertise. One State Health Department (California) is using the indirect immunofluorescence assay (IFA) as a confirmatory test at HIV counseling and testing sites. This test relies on the reaction of serum HIV antibodies to HIV virus present in laboratory cultured HIV-infected cells. When serum is added to the infected cells, any antibody that is present binds to the viral antigens. Fluorescein-labeled goat antihuman globulin is then used to detect the presence of intracellular HIV antibodies. Results are read with a fluorescent microscope (253). A commercial indirect immunofluorescence assay was being evaluated by the Food and Drug Administration (FDA) as a confirmatory test as of early 1988 (IND application submitted to the FDA) (184).

An alternative to the usual Western blot confirmatory test is now available, using six recombinant DNA-derived HIV antigens (3 are proteins derived from gp120 and gp41; 2 are portions of core proteins p24 and p55; and one is a peptide derived from polymerase proteins). The test, called

Hivagen, is available as a laboratory service through SmithKline Beckman. Advantages over the usual Western blot include reduced false positive and indeterminant results and an ELISA format, which allows for automated testing and objective interpretation of results (242). Reactivity to envelope antigen plus either core or polymerase (enzyme) antigen constitutes a Hivagen-positive test (190).

## Tests To Detect the Presence of HIV

There are methods available to detect the presence of HIV itself instead of antibodies to HIV. Direct observation of the virus or signs of viral activity can be made following successful culturing of HIV. However, culturing peripheral blood mononuclear cells may take 2 weeks or longer and is expensive and technically difficult to perform. However, one company has established a commercial laboratory dedicated solely to AIDS testing and eventually plans to use a semi-automated culturing technique. At present the laboratory uses a manual process that provides results in 6 to 14 days (188).

*In situ* hybridization involves the use of radioactively labeled probes to identify HIV-produced RNA or DNA. These genetic probes, produced through recombinant DNA technology, are complementary to the virally produced genetic material and therefore align to and hybridize with it. The method was previously of limited utility, because very few circulating white blood cells are infected with HIV. However, Cetus Corporation has recently developed a method for greatly amplifying the number of infected cells from a few infected cells (82). *In situ* hybridization has been used to diagnose HIV infection in newborns. (As mentioned previously, difficulties arise in diagnosing infants of HIV-infected mothers, because the mother's antibodies to the virus are transferred to the infant during pregnancy. Assays for IgM antibodies, which might be used to differentiate the infant's antibodies from its mothers (i.e., IgG antibodies) are also under development to assist in the diagnosis of HIV infection in the newborn.

## Indirect Methods To Test for Possible HIV Infection

Before HIV antibody tests were available, some blood banks screened donors using a test for antibodies against the hepatitis B core antigen following reports that as many as 80 percent of AIDS patients had evidence of previous hepatitis infection. At least one blood bank determined T4/T8 lymphocyte ratios to identify possibly immunosuppressed donors. As previously described, some insurance applicants are being tested for T-cell abnormalities. T-cells have characteristic surface markers (antigens). T4 cells (helper-cells) carry the CD4 antigens, and T8 cells (suppressor-cells) carry CD8 antigens. The AIDS virus has an affinity for the CD4 antigen on T lymphocytes and consequently, individuals with various manifestations of HIV infection often have a deficiency of T4 cells and a reversal of the usual ratio of T4 to T8 cells. The T4/T8 ratio can be measured by an automated method of sorting and counting labeled T-cells (flow cytometry, using a fluorescence-activated cell sorter).

The T4/T8 cell test is not very predictive of HIV infection. Advanced age and acute infections are associated with positive test results. And as described earlier, the T-cell test does not accurately identify those that are infected.

There are two other indirect tests of Human Immunodeficiency Virus (HIV) infection. The measurement of urinary or serum neopterin and beta$_2$-microglobulin levels has been described as immunological tests that may be useful in the diagnosis of viral infections, including HIV. Both neopterin and beta$_2$-microglobulin are markers for activation of cell-mediated immunity. While elevated neopterin and beta$_2$-microglobulin levels have been noted in individuals with AIDS and American Red Cross (ARC), elevated levels have not been consistently associated with the HIV-infected, but asymptomatic, state (129). Furthermore, both markers are non-specific. For example, neopterin is elevated in many individuals with bacterial and viral infections (e.g., staphylococcal pneumonia) (222). The medical community rarely uses these tests for diagnostic purposes, and there is no evidence that insurers are using neopterin or beta$_2$-microglobulin levels in underwriting applicants.

## Accuracy and Reliability of Commercially Available HIV Screening Tests

HIV testing errors may occur because of intrinsic limitations of the tests themselves, laboratory errors in performing the tests, mislabeling, and inaccurate communication of results. The accuracy of a diagnostic test is usually measured in terms of its sensitivity and specificity. Sensitivity is a function of how well a test correctly identifies affected individuals, and specificity describes a test's ability to correctly identify those that are unaffected (figure 4-2). A sensitivity of 99.3 percent means that for every 1,000 screening tests on positive specimens, on average 7 would be incorrectly identified as negative. A specificity of 99.7 percent means that for every 1,000 negative samples screened, on average 3 would be incorrectly identified as positive.

There is no "gold standard" against which the performance of new screening tests for HIV infection can be compared. Instead, measurements of test sensitivity and specificity are based on testing those with clinically diagnosed AIDS and those without known exposures or risk factors. Using these populations, the ELISA HIV-antibody tests are between 99 and 100 percent sensitive and specific (see table 4-4). However, these measurements would be flawed if some "normal" specimens assumed to contain no HIV antibodies indeed contained them. Moreover, some persons meeting the clinical definition of AIDS do not have detectable levels of HIV antibodies.

A number of investigators have evaluated the performance of ELISA screening tests by applying the tests to Western blot-confirmed positive and negative samples, rather than reporting the performance of tests when applied to presumptively positive and negative samples. When evaluated against Western blot-confirmed samples, the sensitivity of commercially available tests ranged from 97 to 100 percent, and the specificity, from 70 to 100 percent (117). Differences have also been noted between the ability of various commercial test kits to identify early infections (254). Some investigators have reported variations in test results when identical ELISA kits from the same manufacturer have been used by different laboratories; and within a lab, batch-to-batch variation has occurred (224).

**Figure 4-2.—Results of Screening Test Illustrating Sensitivity and Specificity**

| Result of screening Test | Disease state | |
|---|---|---|
| | Disease | No disease |
| Positive | *true positive* TP | false positive FP |
| Negative | false negative FN | *true negative* TN |

$$\text{Sensitivity} = \frac{TP}{TP + FN} \qquad \text{Specificity} = \frac{TN}{TN + FP}$$

Percentage sensitivity = percentage of people with the disease who are detected by the test = $\frac{TP}{TP + FN} \times 100$

Percentage false negatives = percentage of people with the disease who were not detected by the test = $\frac{FN}{TP + FN} \times 100$

Percentage specificity = percentage of people without the disease who were correctly labelled by the test as not diseased = $\frac{TN}{TN + FP} \times 100$

Percentage false positives = percentage of people witnout the disease who were incorrectly labelled by the test as having disease = $\frac{FP}{TN + FP} \times 100$

NOTE: Predictive value of a positive test = $\frac{TP}{TP + FP} \times 100$

SOURCE: Office of Technology Assessment adapted from J. Mausner and A. Bahn, *Epidemiology: An Introductory Text*, 2nd ed. (Philadelphia, PA: W.B. Saunders Company, 1985).

The predictive value (the percent of positives that are true positives) improves with the prevalence of infection among those screened. For example, suppose the ELISA test can be conducted with a sensitivity of 100 percent and a specificity of 99.8 percent. If the prevalence of antibodies against HIV in the tested population was 0.1 percent (1 in 1,000), only one-third of positive ELISA tests would actually be positive. In contrast, if the prevalence were 10 percent, 98 percent of positive ELISA tests would be truly positive (see figure 4-3 and table 4-5). Therefore, even with a highly sensitive and specific screening test, errors will occur, and errors will increase as populations with lower and lower levels of infection are screened (196). Confirmatory tests are therefore necessary to avoid falsely identifying persons as being infected.

The Western blot is much more specific than the ELISA and is therefore useful in correctly identifying those that are truly negative. However, both false positive and false negative Western blots have been reported. For example, as a part of the U.S. Army quality assurance program for HIV testing, a panel of fifteen repeatedly negative serums from healthy adults were sent to five commercial laboratories offering HIV Western blot testing. Six different specimens were classified as positive (four of five of the labs made at least one error; one lab made three errors). This suggests that the errors were due to technique and not to intrinsic biologic properties of the specimens. In addition, five confirmed positive samples were sent to each of the five laboratories. One laboratory falsely identified an HIV positive specimen as negative. In light of these findings, the U.S. Army has adopted a number of policies aimed at minimizing errors in the interpretation of Western blot tests (36).

**Figure 4-3.—Predictive Value Calculation for Prevalence of 10 Percent; Test Sensitivity = 100%, Specificity = 99.8%[a]**

| | | *Antibody present*<br>Yes | <br>No |
|---|---|---|---|
| *Test positive* | Yes | True positive<br>1,000 | False positive<br>18 |
| | No | False negative<br>0 | True negative<br>8,982 |
| | | 1,000 | 9,000 |

Predictive value = $\frac{1,000}{1,018}$ = 98.2 percent

[a]Assume that 10,000 persons are tested.

SOURCE: Office of Technology Assessment, 1988.

**Table 4-5.—Relationship Between Predictive Value and Prevalence of the Index Condition in the Population Being Screened[a]**

| Prevalence | Predictive value of a positive test |
|---|---|
| 10 percent | 98.2 percent |
| 5 percent | 96.3 percent |
| 1 percent | 83.5 percent |
| 0.1 percent | 33.2 percent |
| 0.01 percent | 4.8 percent |

[a]Assumes test sensitivity of 100 percent and specificity of 99.8 percent.

SOURCE: Office of Technology Assessment, 1988.

According to proficiency testing data, the performance of HIV testing is not as accurate under "usual" conditions of use as that reported under ideal conditions of use. Results of the College of American Pathologists' (CAP) proficiency testing program from more than 500 laboratories participating in the 1986 and 1987 CAP surveys reveal that of 6,946 ELISA HIV-antibody tests on reactive samples, 99.5 percent were reported as positive and on the 1,142 HIV-antibody negative samples, 98.3 percent were interpreted as negative.

For the Western blot test, the results of only the October 1987 test were analyzed, consisting of three reactive and one nonreactive samples. Of the tests on the 3 reactive samples, 89.2 percent (215 of 241 tests) were interpreted correctly as positive; 23 were reported as indeterminant and 3 were reported as negative. Of the 58 tests performed on the nonreactive sample, 94.8 percent (55 of 58) were correctly interpreted as negative; 3 were reported as indeterminant. The performance of reference laboratories (selected laboratories with good performance records) was more accurate for ELISA and much more accurate for the Western blot tests than was the performance of the other participating laboratories. None of the laboratories participating in Western blot testing reported a negative specimen as positive. When they erred, the results were reported as indeterminate. However, as only one nonreactive sample's results were analyzed, whether labs have in fact never reported nonreactive samples as positive by Western blot is not known. Unfortunately, performance with the licensed versus unlicensed Western blot tests could not be compared, because the data were not collected (206).

These results most likely underestimate problems in HIV-antibody testing, as the proficiency testing was "open"—i.e., the laboratories knew they were being evaluated and knew that these were test samples. "Blind" performance testing in which participating laboratories are unaware that they are being evaluated would be a more accurate assessment of laboratory HIV-antibody testing proficiency. (In a further effort to assess the quality of the performance of HIV tests, the Center for Disease Control (CDC) will also implement a nationwide performance evaluation program for HIV antibody testing, but this program too will be of the "open" type, and participation in the program will be voluntary (205).

## Advances in HIV Screening Technology

A number of new screening products are under development that will improve the accuracy of HIV testing, and some of these tests are already available for research use.

"Second generation" antibody screening test kits that contain viral components derived from genetic engineering techniques are likely to reduce the number of false positive screening results attributed to contaminants from cell culture present in the first generation tests. Some evidence suggests that these assays may detect infection earlier than the first generation tests (166). In addition to being possibly more accurate than the first generation tests, some of the second generation kits will take less time to process (5 to 30 minutes as opposed to 2 to 4 hours) and may be less expensive.

These very specific HIV-antibody tests may eventually replace the Western blot confirmatory test. An ELISA that uses a short, synthetic peptide that mimics the immunoreactivity of whole HIV is currently being investigated. Nonspecific reactions leading to false positives on Western blot would be eliminated, because a single HIV immune site would be used. However, false-negatives may occur if there are variant HIV strains without the specific immune site. To overcome this problem, a panel of synthetic peptides may be used that covers all HIV strains (192).

Although not yet commercially available, two companies have developed antigen enzyme immunoassays to detect p24 antigen. The presence of endogenous antibodies to HIV interferes with such assays and therefore limits their use (i.e., after an individual produces HIV antibodies, the antigen test may be negative). The HIV antigen enzyme immunoassay has been used to diagnose acute HIV illness in high-risk patients at a time when they have not yet developed HIV antibodies (155). Although the sensitivity and specificity of the HIV-antigen immunoassays are as yet unknown, they may be useful in screening blood products, identifying acute HIV infections, and monitoring the course of therapy for AIDS/ARC patients.

Genetic probes are being developed to recognize viral DNA or RNA sequences (viral genetic material) in cells (209). (Genetic probes are labeled gene sequences synthesized to be complementary to viral sequences.) Probe-based tests will be useful in identifying HIV-infected individuals who do not have detectable virus in their blood. While there are technical difficulties that remain in perfecting DNA probe tests, some of these difficulties have been surmounted. As mentioned previously, the Cetus Corporation has developed a process whereby viral DNA sequences can be multiplied a million times, making it possible to detect viral genes even if present in only one of every 5,000 cells (82).

All of the commercially available screening tests are performed on blood or serum samples. One team of investigators has applied a variant of these tests (IgG-capture radioimmunoassays and ELISA assays) to saliva samples. Almost total qualitative agreement was found in results between paired serum and saliva samples (pairs of samples were both identified as positive or negative); but for quantitative agreement, actual test values for paired samples were not highly correlated (229). Finally, recent investigations have determined that HIV antibodies can be found in urine, and whether this finding will be useful in using urine for HIV-antibody testing is under investigation (40).

Table 4-6 identifies the HIV diagnostic products under development as of early 1988.

Table 4-6.—HIV Diagnostic Products Under Development in Spring 1988

| Manufacturer | Product name | Indication |
|---|---|---|
| **Products pending FDA approval:** | | |
| Abbott Laboratories | to be announced | detects HIV antigens |
| Abbott Laboratories | Envacor | detects antibodies to core antigen p24 and the envelope antigen p41 |
| American Bionetics | Wesblot | automated Western blot |
| Cambridge Bioscience (Worcester, MA) | Recombigen Latex HIV (rapid HIV antibody test) | detects HIV antibodies |
| Cambridge Bioscience | Recombigen EIA HIV (two-hour immunoassay) | detect HIV antibodies |
| Du Pont | HIV p24 core antigen test | detects HIV p24 core antigen |
| Electro-nucleonics | Virgo HIV IFA (immunofluorescence assay) | detects HIV antibodies |
| Hoffman-La Roche (Nutley, NJ) | to be announced | detects HIV antibodies |
| **Products in development:** | | |
| Cetus (Emeryville, CA), Eastman Kodak | SureCell | detects HIV antibodies |
| Cetus, Eastman Kodak | to be announced | amplifies and detects HIV viral DNA |
| Syntex/Syva (Palo Alto, CA), Cambridge Bioscience | to be announced | test for AIDS antibodies |
| Viral Technologies (Interleukin-2, Alpha-1 Biomedicals) (Washington, DC) | to be announced | detects HIV p17 antibodies |
| **Products in clinical trials:** | | |
| Chiron (Emeryville, CA), (Ortho Diagnostics, marketer) | RIBA HIV216 | validates results of positive ELISA test |
| Du Pont | Rapid HIV antibody test | detects HIV antibodies |
| MicroGeneSys (West Haven, CT) | MGSearch HIV-160 | detects HIV antibodies |
| Thermascan (New York, NY) | Fluorognost (immunofluorescence assay) | HIV-1 antibody confirmation test |
| **Products in research:** | | |
| Gen-Probe (San Diego, CA) | to be announced | test for AIDS virus |
| Syntex/Syva | to be announced | test for AIDS virus |

SOURCE: Adapted from Pharmaceutical Manufacturers Association, "Pharmaceutical Industry Response to the AIDS Crisis," Washington, D.C., Feb. 19, 1988.

## HIV Self-Tests

Tests for HIV infection that can be performed at home are not currently available, although tests have been developed that could be used as home tests. For example, Cambridge Bioscience has developed a rapid test for HIV infection that can be used on whole blood. The company plans to limit sales to physician offices and health clinics (219). Although tests have been developed that may be simple enough to use on samples collected at home, they have not been approved by FDA for these purposes. In fact, the FDA has notified companies planning to enter the self-testing market of medical guidelines restricting HIV test kit use to professionals working within comprehensive health care environments (107).

Several companies had planned to sell kits that allowed the purchaser to collect his own blood, send it anonymously in a prepaid package to a clinical laboratory, and obtain the results of ELISA screening tests (without Western blot confirmation) by phone (189). People anxious to learn about their antibody status but reluctant to see their physicians or to use alternate test sites were expected to use such services (193). Among the concerns that FDA raised in considering mail-in tests were: 1) test results would be provided with limited or no counseling, 2) confirmatory testing was not being offered, 3) the quality of testing would depend on the integrity of mailed samples, and 4) as health professionals would not be involved in the testing process and testing would be anonymous, compliance could decline with the requirement to report the names of those testing positive to State Health Departments in States that have this requirement (e.g., Colorado and Arizona).

## GENETIC TESTS

### Introduction

Advances in molecular genetics have led to the development of a number of new diagnostic and therapeutic products. Human insulin, growth hormone, and promising drugs for individuals with heart disease have been developed through recombinant DNA technology. In the area of diagnostics, this technology has been used to improve a number of tests for infectious diseases, including HIV tests. While several recombinant DNA diagnostic tests are now being marketed for infectious disease applications, a larger market for diagnostics may be realized when tests for common disorders with a genetic component are developed. Several tests for relatively rare genetic conditions are already available using this new technology. However, they rely on relatively sophisticated techniques, are difficult to interpret, and are therefore available at only a few specialized laboratories. As technological hurdles are overcome, and as advances in molecular genetics continue to be made, new genetic tests may revolutionize the practice of medicine. Tests will improve the diagnosis of suspected genetic disorders and may be widely applied to identify those predisposed to common disorders with a genetic basis. In some cases, early intervention will prevent or ameliorate manifestations of the diagnosed condition.

Although many genetic disorders are rare, collectively they constitute a major source of morbidity and mortality. Evidence suggests that specific genes predispose individuals to some forms of diabetes, heart disease, cancer, and mental illness (267). When the prevalence of these conditions is considered, the potential impact of genetic tests becomes clear. Table 4-7 summarizes one market prediction of the number of DNA-probe tests by type of disease that may be in use by 1992. Table 4-8 summarizes the projections of several recent market forecasts. These projections probably overestimate the 1992 genetic test market (42) but indicate that tests may soon be available for a variety of genetic disorders and predispositions, and when available, increasingly used in medical practice. As some of these tests are for can-

**Table 4-7.—DNA Probe Test for Inherited Diseases**

| Disease | Number of tests per year | Value (millions) |
|---|---|---|
| **Purely genetic diseases:** | | |
| Adult polycystic kidney | 250,000 | $ 7.5 |
| Cystic fibrosis | 333,000 | 10.0 |
| Duchenne muscular dystrophy | 333,000 | 10.0 |
| Familial hypercholesterolemia | 250,000 | 7.5 |
| Familial polyposis | 165,000 | 5.0 |
| Huntington's disease | 20,000 | 0.6 |
| Neurofibromatosis | 250,000 | 7.5 |
| Retinoblastoma | 250,000 | 7.5 |
| Sickle cell anemia | 250,000 | 7.5 |
| Other | 500,000 | 15.0 |
| Subtotal | 2,601,000 | $ 78.1 |
| **Common diseases with a genetic component:** | | |
| Alzheimer's disease | 1,000,000 | $ 30.0 |
| Cancer | 12,000,000 | 360.0 |
| Diabetes mellitus | 5,000,000 | 150.0 |
| Heart disease | 12,000,000 | 360.0 |
| Subtotal | 30,000,000 | $900.0 |
| Total | 32,601,000 | $950-1,000 |

SOURCE: Genetic Technology News, "Market for DNA Probe Tests for Genetic Diseases," *Gen. Tech. News*, pp. 6-7, November 1986.

### Table 4-8.—Genetic Test Market Projections

| Type of disease[a] | U.S. market value ($ million) | By projected year | Source |
|---|---|---|---|
| Genetic & genetic predispositions | 210 | — | Biomedical Business International, 1986 |
| Genetic | 500 | 1993 | Genetic Engineering News, 1986 |
| Genetic (includes laboratory revenues and identity testing) | 550 | 1990 | Robert S. First, 1986 |
| Genetic, infectious and cancer | 300-500 | 1995 | Genetic Engineering News, 1987 |
| Genetic | 150 | 1995 | Frost & Sullivan, 1985 |
| Genetic & genetic predispositions | 950-1,000 | 1992 | Genetic Technology News, 1986 |

[a] 'Genetic' refers to single gene disorders (e.g., cystic fibrosis, sickle cell anemia) and chromosomal disorders (e.g., Down syndrome). 'Genetic predispositions' refer to common disorders known to have a genetic component such as heart disease and diabetes.

SOURCE: Office of Technology Assessment, 1988.

cer, diabetes, or heart disease, they would appear to be of considerable interest to insurers. However, it is important to understand some of the technical characteristics and limitations of these tests before concluding that they will be adopted by insurers or employers.

Tests for genetic disorders have, to date, been used almost exclusively within the disciplines of pediatrics and obstetrics. For example, in all States, newborns are screened for one or more genetic conditions amenable to effective treatment (e.g., phenylketonuria), and pregnant women 35 and older are routinely offered prenatal diagnosis to detect fetal chromosomal abnormalities such as those associated with Down's Syndrome. Aside from pediatric and obstetric applications, genetic testing has not yet become widely incorporated into the practice of medicine. Genetic screening programs targeted at young adults have generally involved specific racial and/or ethnic groups and have usually addressed reproductive risk rather than the presence of disease itself. For example, community-wide programs to identify carriers of sickle-cell disease or Tay-Sachs disease have been implemented to identify those couples who might benefit from genetic counseling and prenatal diagnosis.

Most available tests for genetic conditions are not based on recombinant DNA techniques. In fact, until recently, three basic approaches have been used to diagnose genetic conditions. First, chromosomal analyses are employed to detect conditions such as Down's syndrome. Tests for chromosomal abnormalities can be conducted with blood, with the fetal cells contained in amniotic fluid, or more recently, with chorionic villus samples (obtained during the first trimester of pregnancy). Second, biochemical assays to identify abnormal gene products or the consequences of abnormal gene function have been used. In the case of Tay-Sachs disease, for example, reduced activity of the enzyme, Hexosaminidase A, signals either the disease or carrier state. Lastly, genetic testing has relied on identifying clinical manifestations of the disease itself. Table 4-9 summarizes information on some common genetic disorders.

Most conventional genetic tests rely on detecting the products expressed by abnormal genes. As the gene product associated with most genetic disorders is unknown, there are relatively few genetic tests available. In some cases, the development of tests has been stymied by the inability to access tissues in which gene product abnormalities may be found (e.g., brain, eye). Many available tests are also of limited use, because irreversible damage may have already occurred by the time an abnormality in gene function is detected.

Since the 1970s, a variety of techniques has been developed that allow a more direct examination of the genes themselves. DNA-based tests overcome many of the limitations of conventional tests for genetic disorders. They can be of diagnostic use without knowing the gene's product or function; furthermore, because genes are present in virtually all body cells, tests can be applied using easily accessible tissues such as white blood cells, and in the case of prenatal diagnosis, fetal cells can be obtained through amniocentesis or chorionic villus biopsy. With an individual's genetic

### Table 4-9.—Common Genetic Disorders

| Genetic disease | Cause | Nature of illness | Incidence | Inheritance |
|---|---|---|---|---|
| Down syndrome | autosomal chromosome abnormality | range of mental retardation | 1 in 800 | sporadic |
| Klinefelter's Syndrome | sex chromosome abnormality | defect in sexual differentiation | 1 in 2,000 | sporadic |
| Cystic fibrosis | ? | complications of excessively thick mucus secretion | 1 in 2,000 Caucasians | autosomal recessive |
| Huntington's disease | ? | progressive mental and neurological degeneration | 1 in 2,500 | autosomal dominant |
| Duchenne muscular dystrophy | ? | muscular degeneration, weakness | 1 in 7,000 | X-linked |
| Sickle-cell disease | abnormal hemoglobin | impaired circulation, anemia, pain attacks | 1 in 625 mostly black | autosomal recessive |
| Hemophilia | defect in blood clotting factors | uncontrolled bleeding | 1 in 10,000 | X-linked |
| Phenylketonuria | enzyme deficiency | mental deficiency | 1 in 12,000 mostly Caucasians and Orientals | autosomal recessive |
| Tay-Sachs disease | absence of an enzyme | buildup of fatty deposits in brain, leading to early death | 1 in 3,000 Ashkenazic Jews | autosomal recessive |
| Lesch-Nyhan syndrome | enzyme deficiency | mental retardation, self-mutilation | 1 in 100,000 | X-linked |

SOURCE: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of General Medical Sciences, "The New Human Genetics," NIH Pub. No. 84-662 (Washington, DC: U.S. Government Printing Office, 1985).

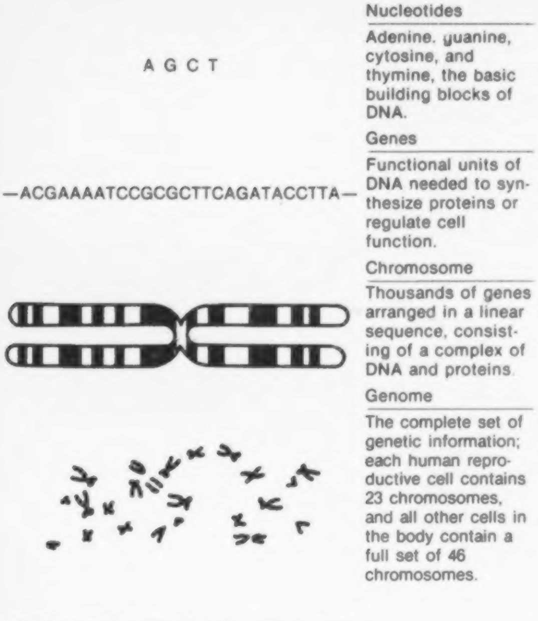
makeup determined at conception, DNA-based tests can be administered pre- or post-natally and before the onset of symptoms of the disease. Early diagnosis affords the possibility of therapeutic intervention to prevent manifestations of disease. As genes that are associated with an increased risk of common disorders such as heart disease and diabetes are identified, tests may be applied widely, perhaps as part of a population screening effort. Before describing the newer genetic diagnostic methods, a review of some basic genetic principles is in order.

## Some Basic Genetic Principles: A Review

Genes are lengths of deoxyribonucleic acid (DNA) that have three main functions: 1) they code for polypeptide chains, the components of proteins; 2) they have important regulatory functions; and 3) they self-replicate during cell division. The human genome contains an estimated 100,000 genes arranged along the length of chromosomes (figure 4-4). DNA is a macromolecule made up of two chains containing four nucleotide bases—adenine, guanine, cytosine, and thymine or A, G, C, and T. The two chains are complementary. The adenine base on one chain will always bind with the thymine base on the other, and cytosine on one chain always binds with guanine on the other. Hydrogen bonds hold the bases of the two chains together to form a spiraling helix (the double helix). To illustrate the concept of the complementary nature of the two chains, if one strand had the base arrangement of CCAT, its complementary strand would be GGTA (figure 4-5).

The location of a gene along the length of DNA is called its *locus*. Because chromosomes occur in pairs (humans have 23 pairs), there are two copies of a gene at each locus, one inherited from each parent. Different "versions" of a gene at a particular locus are called *alleles*. When there are two or more versions (alleles) of a gene at a par-

**Figure 4-4.—Organizational Hierarchy of DNA, the Carrier of Genetic Information in Human Cells**



Nucleotides

Adenine, guanine, cytosine, and thymine, the basic building blocks of DNA.

Genes

Functional units of DNA needed to synthesize proteins or regulate cell function.

Chromosome

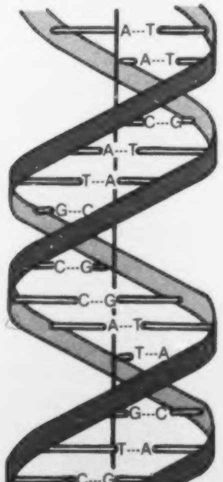
Thousands of genes arranged in a linear sequence, consisting of a complex of DNA and proteins.

Genome

The complete set of genetic information; each human reproductive cell contains 23 chromosomes, and all other cells in the body contain a full set of 46 chromosomes.

SOURCE: Office of Technology Assessment, 1987.

**Figure 4-5.—A Schematic Diagram of the DNA Double Helix**



SOURCE: Office of Technology Assessment, 1987.

ticular locus and the allele has a frequency of at least 1 percent in the population, the genetic variant is referred to as a *polymorphism*.

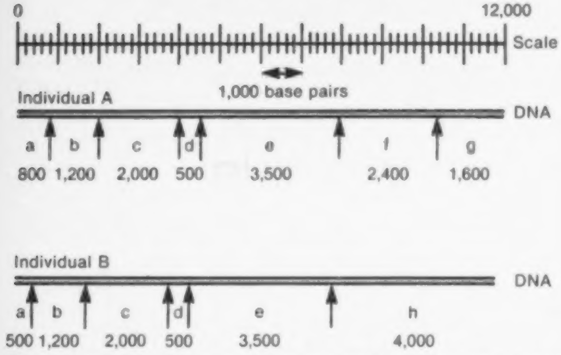
Given the variety in human characteristics, it is not surprising that there is variability in the DNA sequence. Some of the variability is significant in that a change in the expression of the gene results. In some cases, this change causes disease; in other cases, no disease. Other variations in genes occur but have no effect on gene expression.

A number of techniques has been developed that help identify genetic variation at the DNA level and consequently assists in distinguishing between those with disease-causing alleles from those with normal alleles. There are two basic approaches. In the *linkage method* DNA markers associated with abnormal alleles within families are used to predict family members' risks. Second, when the disease-causing alleles have been identified, *direct genetic tests* can be used.

**Linkage methods.**—The discovery of enzymes called "restriction enzymes" that cut DNA at specific sites has contributed to the development of linkage tests. This method exploits the variation that occurs along the length of DNA. The action of the restriction enzymes is sometimes affected by this variability. For example the restriction enzyme EcoRI cuts at the base sequence GAATTC on one DNA strand and at CTTAAG on the other. Following the action of this restriction enzyme, the sequence AAT*GAATTC*GT would be cleaved into two segments of DNA. If, however, an individual had a different sequence at the recognition site, say AAT*AAATTC*GT, the restriction enzyme would not cleave the DNA and there would be one long sequence. These differences in DNA fragment length after subjecting DNA to the action of restriction enzymes are called *restriction fragment length polymorphisms* or *RFLPs* (figure 4-6). More recently, synthetic DNA cutters have been made that will enable researchers to cleave DNA anywhere along its length (272).

Investigators have studied the "inheritance" of RFLPs in families in which a genetic disease occurs. Once it has been established that a particular RFLP is almost always present in individuals with a disease and is almost always absent in those without the disease, the RFLP can be used as a

**Figure 4-6.—Restriction Fragment Length Polymorphism (RFLP)**



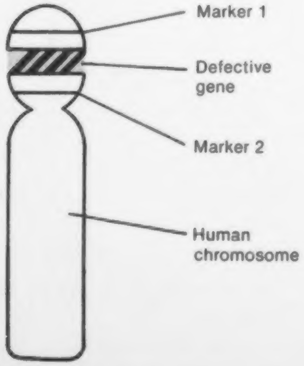
When a specific restriction enzyme cuts DNA, it may produce fragments of different sizes in the DNA of different people.

SOURCE: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of General Medical Sciences, "The New Human Genetics," NIH Pub. No. 84-662 (Washington, DC: U.S. Government Printing Office, 1985).

marker for that disease (different polymorphisms may be associated with the same disease in different families). Such RFLP disease markers are in close physical proximity along the length of DNA to the disease-causing gene (figure 4-7). How linkage analysis works is well illustrated in the case of Huntington's disease (figure 4-8).

In order to conduct linkage analyses, geneticists must usually have blood samples from more than one affected family member. In addition, sometimes at least two generations of family members must be tested. Once blood samples are obtained, DNA must be purified from white blood cells. Next, a technique called Southern blotting is used to visualize individual RFLP patterns (figure 4-9). First, the DNA is cut into fragments with restriction endonucleases. The fragments resulting from the digestion are then placed on a gel and a charge is applied (a process called electrophoresis) (figure 4-10). Because of their different sizes, the fragments migrate along the gel at different speeds and segregate. Labeled probes are prepared (copies of the different RFLPs are made and labeled) and applied to the gel. Both the DNA fragments and probe are "denatured," making them single-stranded. The single-stranded probe then binds to (hybridizes with) complementary DNA sequences. Because the probe is labeled (either radioactively or with Biotin, a nonradioactive chemical), distinct bands representing the fragments of different lengths can be visualized.

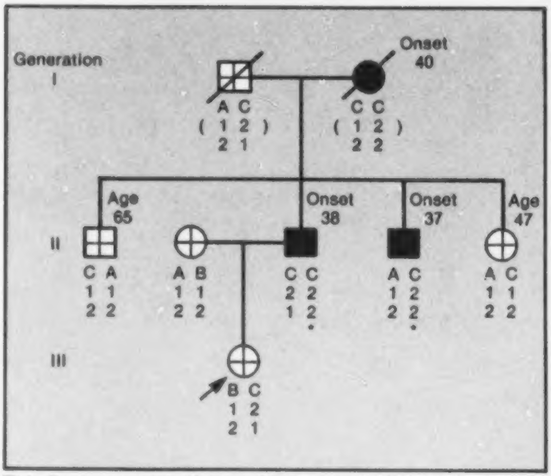
**Figure 4-7.—Genetic Linkage**



Discovering specific DNA markers near a defective gene greatly improves the accuracy of diagnosing the genetic disorder.

SOURCE: Integrated Genetics Inc., "Annual Report 1985," Framingham, MA, 1986.

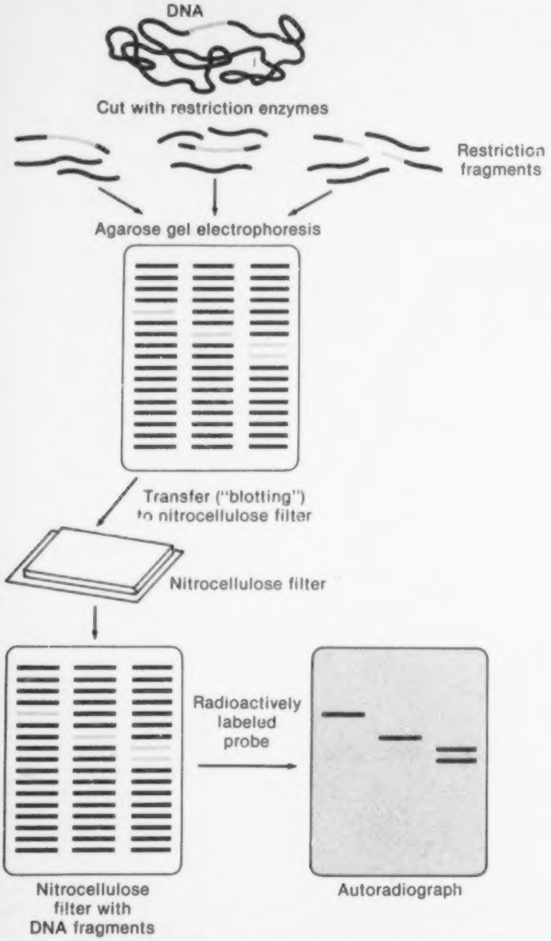
**Figure 4-8.—Linkage Analysis for Huntington's Disease (HD)**



This figure presents the result of a genetic linkage test using three different restriction enzymes. The first produces four possible RFLP's listed as A, B, C, or D: the second and third enzymes produce two RFLP's listed as 1 or 2. The three RFLPs for each of the two number 4 chromosomes are presented vertically under each individual. In this example an at risk consultant had an affected father and uncle and an affected grandmother who is deceased. The form of the RFLP linked to the HD gene appears to be C22 since this is the RFLP that the father and uncle have in common. The consultant had inherited a B12 from her mother and a C21 from her father and therefore has probably not inherited the HD gene.

SOURCE: R. Myers, "Genetic Linkage Test for Huntington's Disease," *The Genetic Resource* 4(1):15-18, 1987.

Figure 4-9.—Southern Blotting

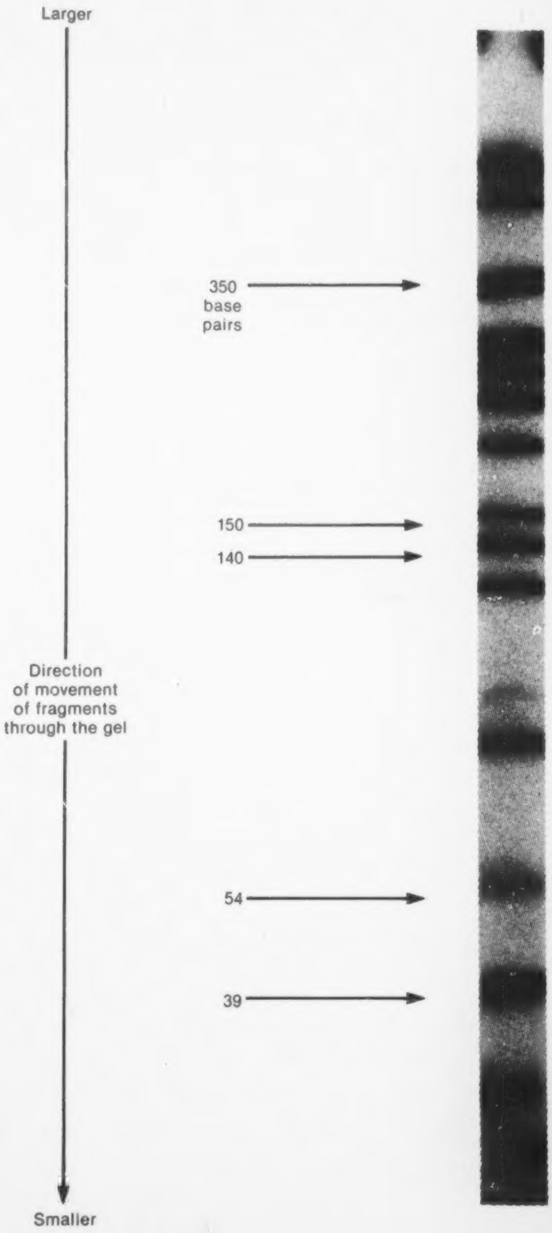

DNA
Cut with restriction enzymes
Restriction fragments
Agarose gel electrophoresis
Transfer ("blotting") to nitrocellulose filter
Nitrocellulose filter
Radioactively labeled probe
Nitrocellulose filter with DNA fragments
Autoradiograph

SOURCE: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of General Medical Sciences, "The New Human Genetics," NIH Pub. No. 84-662 (Washington, DC: U.S. Government Printing Office, 1985).

The use of linkage tests is limited, because the exact location of the deleterious gene is not known. Instead, an analysis of the transmission of linked markers within families in which the disease occurs forms the basis of the test. Because these analyses require the cooperation of multiple family members, they are not widely applicable. When affected family members are deceased, or when communication regarding the disease is poor, such testing efforts can be hampered.

Because linkage analyses track the inheritance of a marker close to the disease-causing allele, it

Figure 4-10.—Electropheresis Preparation of a Southern Blot


Larger
350 base pairs
150
140
Direction of movement of fragments through the gel
54
39
Smaller

SOURCE: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of General Medical Sciences, "The New Human Genetics," NIH Pub. No. 84-662 (Washington, DC: U.S. Government Printing Office, 1985).

is vitally important to accurately categorize those represented in the family tree (pedigree) as affected or unaffected. Sometimes the diagnosis of genetic conditions such as Huntington's disease, for which no definitive diagnostic test is available, are subject to error. Alcoholism, multiple sclerosis, and a number of other neurologic disorders have been misdiagnosed as Huntington's disease. In addition to ensuring that family members participating in linkage analysis are correctly identified as affected or unaffected, sometimes evidence of paternity is sought for those participating in the family studies to further guarantee the accuracy of the tests.

Even when the appropriate family members are available and the diagnosis of the genetic condition is well established, linkage tests may not be informative. For the tests to be informative, family members must be polymorphic (i.e., have different versions of the allele) at the relevant restriction site(s). In the case of Huntington's disease, some families cannot benefit from linkage analyses because they lack "heterogeneity" for the RFLP. That is, those with the disease have the same base pairs at the restriction site close to the deleterious gene as unaffected members. Even for those families that show variation and can be studied using linkage analyses, the risk of being affected for any particular family member (or fetus in the case of prenatal diagnosis) is rarely given as zero or 100 percent. The certainty with which diagnoses are made depends on how tightly linked the marker is to the disease-causing allele.

As the distance between the marker and the deleterious gene increases, the chance of an exchange of DNA between chromosomes (called "crossing over") within this region during meiosis (the cell division occurring at the time of conception) increases. If the exchange took place between the marker and the disease-causing allele, an erroneous linkage study result would occur. Diagnostic certainty increases when there are two RFLP markers flanking the deleterious gene. Flanking markers have been identified for cystic fibrosis, so when a family undergoes linkage testing, the chance that the results represent their true genetic state is very high. Sometimes, the RFLP and the gene are observed to be "very tightly linked." When all of those with disease have one form of an RFLP and those without disease have another form, the association suggests that the polymorphic restriction cleavage site includes the disease-causing gene. Such tightly linked polymorphisms have been observed for phenylketonuria (PKU) and some thalassemias (table 4-10). The specific location of the gene that causes cystic fibrosis has recently been identified (326). When verified, a direct test will become feasible.

For some disorders, spontaneous mutation accounts for a relatively large proportion of cases. For example, in the case of Duchenne Muscular Dystrophy, even though flanking markers for the gene have been located, linkage tests have been reported to be uninformative in many families studied. Some of the inconclusive results occur because an estimated 10 to 15 percent of cases of the disease result from spontaneous mutations that are not inherited.

In summary, linkage studies are unwieldy because they involve multiple family members, are technically difficult to conduct and therefore expensive ($500 to $1,000), and their interpretation is somewhat subjective and requires a great deal of knowledge regarding the expression of the dis-

**Table 4-10.—Available Genetic Tests by Type of Test[a]**

| Test type | Disease |
|---|---|
| Linkage RFLP tests: .... | Becker's muscular dystrophy |
| | Carbamyl phosphate synthetase deficiency |
| | Chronic granulomatous disease |
| | Cystic fibrosis |
| | Fragile X syndrome |
| | Hemophilia A and B |
| | Huntington's disease |
| | Myotonic dystrophy |
| | Neurofibromatosis |
| | Polycystic kidney disease (adult) |
| Direct tests: ........... | Alpha$_1$ antitrypsin deficiency |
| | Duchenne muscular dystrophy |
| | Growth hormone deficiency |
| | Lesch-Nyhan disease |
| | Ornithine transcarbamylase (OTC) deficiency |
| | Retinoblastoma |
| | Sickle cell anemia |
| | Thalassemia (some forms) |
| Tests for very tightly linked polymorphisms: .. | Hemoglobinopathies |
| | Phenylketonuria (PKU) |
| | Thalassemias |

[a] This represents a selected list of tests available as of early 1988.

SOURCE: Office of Technology Assessment, 1988.

order in question. However, with the rapid discovery of more genetic markers, linkage studies will be available for an increasing number of disorders. (Genetic maps have been constructed that already include the relative positions of more than 400 markers (69).)

**Direct Genetic Tests.**—When a disease-causing gene has been identified, direct tests have been developed that avoid many of the problems associated with linkage analyses. Direct tests do not rely on the analysis of multiple family members and therefore may be amenable to population-wide screening. To date, there are few conditions for which these direct tests are available (see table 4-10), and with the exception of sickle cell anemia, the conditions are rare.

The "candidate gene" method can be used to identify disease-causing genes when the product (a protein) of the gene is known or suspected. By working backwards from the gene product, a strand of DNA that is complementary to the gene of interest is created. This is accomplished by taking the messenger RNA (genetic material involved in protein synthesis) for the protein and using the reverse transcriptase enzyme to manufacture a complementary strand of DNA (called cDNA). cDNA can be made for both the normal and abnormal gene products. Once the cDNA has been shown to accurately distinguish affected from unaffected individuals, it can be used as a diagnostic test.

If a disease-causing gene has been located and sequenced, then specific gene probes, complementary to the abnormal gene, can be synthesized, labeled, and used to conduct direct tests using the Southern blot technique. Gene probe tests are available for sickle cell anemia, retinoblastoma, and some forms of thalassemia (see table 4-10).

Three techniques have been developed that will allow the detection of any genetic variation along a particular DNA sequence. The first method relies on the synthesis of short segments of DNA sequences called "oligonucleotides." In order to synthesize oligonucleotides, the amino acid sequence of at least a part of the gene product must be known (if known, the related DNA sequence can be deduced). Testing conditions are manipulated so that these oligonucleotide probes, when applied to a Southern blot, only bind to perfectly complementary sequences. Through comparisons with a sequence of normal DNA, any number of abnormal alleles at a particular locus can be identified (156). A second technique relies on detecting mismatches between a radioactively-labeled RNA probe and an individual's single-stranded DNA. If the DNA includes an abnormal allele, it will not match perfectly to the RNA probe. When the resulting hybrid is mismatched, the enzyme, ribonuclease A, will cut the RNA probe at the site of the abnormal allele (211). The third technique detects differences in the paired probe and DNA sequence according to their migration on a "denaturing gradient gel." A perfectly matched pair of probe and DNA sequence will migrate on a gel differently than a mismatched pair (90).

Until recently, one technical difficulty limiting the use of direct genetic tests was the inability to obtain adequate amounts of DNA, especially when analyzing prenatal diagnostic specimens. A procedure to produce additional DNA from a patient sample has recently been developed (157, 255). After a sample is obtained, an enzyme (DNA polymerase) can be used to amplify targeted DNA sequences more than 200,000-fold. Improvements in this technique have allowed direct visualization of the DNA fragments of interest on standard gels without the use of radio-labeled probes (227). These advances simplify and accelerate the diagnostic process and once automated, will allow more laboratories to conduct DNA-based genetic tests.

## Limitations of Genetic Tests

Although direct genetic tests avoid many of the problems inherent in linkage analyses, both methods may yield inaccurate results because of some unique characteristics of genetic diseases. Some genetic conditions can be caused by more than one mutation, either at the same or at a different locus. For example, G6PD (glucose-6-phosphate dehydrogenase) deficiency may be caused by different mutations at the same locus. In the case of congenital deafness, different recessive genes at different loci can lead to the same clinical picture. And at least two different loci have been implicated in families in which familial manic depression occurs (79,136). Unless such heterogeneity is identified, both linkage-based and some of the direct tests may be misleading.

Another factor that may lead to diagnostic confusion is the extent to which a deleterious gene is expressed, and when expressed, the constancy of its expression. Sometimes, individuals with a genotype associated with disease do not express the disorder at all. Such a condition is said to have reduced "penetrance." For example, retinoblastoma, a dominantly inherited eye cancer, has reduced penetrance. Before an individual who has inherited the abnormal allele expresses it, a mutation must occur in the cells of the eye. Furthermore, some conditions, although expressed, are variable in their expression. Some individuals may be mildly affected, while others are severely affected. In the case of tuberous sclerosis, although the majority of cases represent new mutations, there are cases in which a severely affected child inherited the gene from a very mildly affected parent in whom the disorder had not been recognized.

### Prospects for Genetic Testing

As of the end of 1987, there were no FDA-approved recombinant DNA tests for human genetic conditions (325). Instead, a limited number of tests were available through university genetics programs or through a few commercial laboratories. According to a 1986 survey of biotechnology companies, eight companies plan to offer genetic tests as a laboratory service, and six plan to have diagnostic test kits ready for sale by 1991 (291). One company is in the process of evaluating the predictive value of markers (RFLPs) in detecting an individual's susceptibility to atherosclerosis and hypertension. Cetus Corporation has developed an automated method to amplify DNA and conduct genetic analyses without radioisotopes (82).

Available DNA-based tests for genetic disorders are technically difficult to perform and most rely on the conduct of family studies. As more direct tests become available and as the technologies are simplified, genetic testing may become a part of routine care. However, given the nature of genetic diseases, there will be a significant element of diagnostic uncertainty associated with the tests for many conditions. Heterogeneity, reduced penetrance, and variable expression of some genetic conditions will make predictions difficult based on the results of genetic testing. Furthermore, tests for common disorders with a genetic component (e.g., heart disease, cancers) will rarely be definitively diagnostic. Instead, a positive result from a genetic test would usually mean that an individual's relative risk (relative to those without the gene) is increased. In some cases, modification of lifestyle (cessation of smoking, changes in diet) may reduce the relative risk substantially. In other cases, early medical interventions may alleviate the increased risk.

If genetic tests can provide information that would lead to the adoption of preventive interventions, they may be embraced by primary care physicians. In the past however, primary care physicians have not adopted new genetic tests (51). This may be attributed to the fact that to date, tests have been used primarily to provide reproductive risk information to couples, rather than information regarding the health status of the individuals themselves. Primary care physicians have little exposure to genetics in medical school (47), and there have been few continuing education opportunities directed at the community-based physician. Furthermore, there are few genetic specialists available to offer genetic testing and counseling on a consultative basis (137).

For many diseases there will be a lag period between the time genetic tests are available and the time when effective interventions for the diagnosed condition are available. Other than for reproductive planning, individuals may not find the tests useful. In the case of a debilitating, late-onset condition, however, having risk information early in life may be helpful in making employment and other life decisions. How readily such tests will be adopted remains to be seen. In the case of Huntington's disease, before the announcement of a predictive test, approximately 55 to 80 percent of those at risk indicated that they would elect to be tested when the test became available (258, 275, 285). However, although interest in testing remained high after the announcement of the predictive test (174), in the first several months of testing, less than 15 percent (44/349) of those informed of the test's availability by one of three genetic centers offering the test have requested testing (236).

Will genetic tests be used in underwriting or as part of an employee applicant screening program? The answer depends on many factors. Genetic tests in their present state are impractical to administer, require considerable technical skill both in their conduct and in their interpretation, may require analyses of multiple family members (i.e., linkage-based studies) that would be unacceptably intrusive, and are very expensive to conduct. (A direct test for sickle cell disease may cost as much as $450, and linkage-based tests as much as $1,000.) Once tests are simplified and less costly, and when direct tests for predispositions to common diseases become available, they may be considered attractive to insurers in evaluating an applicant's risk.

Although commercial insurers may be disinclined to test for rare genetic conditions such as Huntington's disease, they would be interested in learning of the results of any genetic tests already conducted by the applicant's physician. Thus, for rare conditions, it appears that the impact of genetic tests on the underwriting process will be felt when genetic tests become a part of routine care.

The availability of genetic susceptibility tests may have a dramatic impact on who the insurer decides to test. At present, a small proportion of applicants are tested. In general these are individuals who indicate a history of disease or presence of a risk factor (e.g., age, hypertension) on the application. As genetic tests can indicate risk in the absence of clinical signs of disease, they may be applied to all age groups to identify risk regardless of medical history. If widely used by primary care physicians in their provision of preventive health care, insurers may be in the position of testing to avoid the prospects of adverse selection.

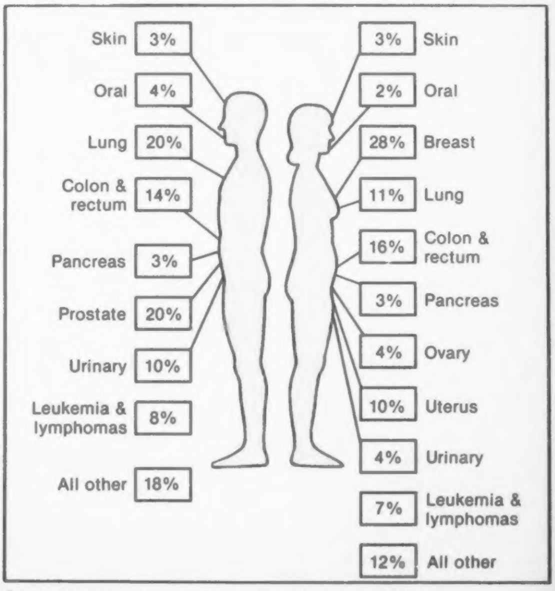
# TESTS OF POTENTIAL INTEREST TO INSURERS BECAUSE OF DISEASE PREVALENCE

## Testing for Cancer

### Currently Available Cancer Screening Tests

Although employers and insurers deal with a relatively young and therefore low-risk population in terms of cancer incidence, a large number of cancers occur among those under 55. Nationally, approximately 19 percent of the estimated 930,000 new cases of cancer occurring in 1986 were diagnosed among those aged 15 to 54 (302, 293). Figure 4-11 summarizes 1988 estimates of the distribution of new cases of cancer by site and sex.

**Figure 4-11.—Distribution of New Cases of Cancer by Site and Sex[a]—1988 Estimates**



[a] Excluding non-melanoma skin cancer and carcinoma in situ.

SOURCE: American Cancer Society, Inc. "Cancer Facts and Figures, 1987," New York, NY, 1988.

Screening tests for latent disease are available for several of the most common cancers (e.g., colon, breast, and uterine/cervical cancers). The American Cancer Society (ACS) has considered the epidemiologic data regarding the impact of screening tests on mortality and has made recommendations to physicians regarding the incorporation of screening into their practices (box 4-A). For example, mammography has been recommended for women 50 and older, based on observed mortality differences between groups of

## Box 4-A.—Screening Tests for Some Common Cancers

**Disease: Colorectal cancer**

Screening Methods:

*Digital rectal examination*: Although widely used as part of routine medical examinations, 90 percent of colorectal cancers are not palpable using the digital rectal examination.

*Sigmoidoscopy*: Using a rigid or flexible scope, physicians can examine from 30 to 60 cm of the colorectum. The flexible scope is more comfortable for the patient but is more difficult for physicians to use. Given the distribution of neoplasms, the flexible scope will miss about 40 percent of cancers (111).

*Stool occult blood test*: There are several commercial fecal occult blood tests available. The most widely used is the Hemoccult II$^{R}$ screening test. The examination of two samples is recommended from each of three consecutive bowel movements while an individual is on a meat-free, high-roughage diet. Individuals are also advised to avoid use of aspirin, nonsteroidal anti-inflammatory drugs, vitamin C, iron, laxatives, rare red meat and fruits and vegetables high in peroxidases (e.g., turnip, cauliflower). Even when used optimally, Hemoccult II$^{R}$ misses as many as 10 percent to 30 percent of cancers and 65 percent to 75 percent of colonic polyps (29). Initial reports on HemoQuant$^{TM}$ a recently introduced quantitative test for occult gastrointestinal bleeding, suggest it is more sensitive than Hemoccult. However, increased detection of upper gastrointestinal tract bleeding and dietary hemoglobin may reduce its specificity (153). Several new methods are being developed that will be more sensitive and specific than current screening methods. For example, immunoassays are being developed that will limit cross reactivity with foodstuffs, animal hemoglobins, and drugs.

Screening recommendations:

*American Cancer Society*: Patients over the age of 40 should have a digital rectal examination annually. They should have a six-slide stool occult blood test annually after the age of 50 years. After age 50, sigmoidoscopy should be done annually for 2 years, then every 3 years.

*Canadian Task Force*: Patients should have an annual stool occult blood test starting at the age of 46 years.

*Epidemiologic data in support of recommendations*: Two prospective controlled trials are ongoing to assess the impact of stool occult blood testing on mortality (106,320). Preliminary data indicate that occult blood testing confers an advantage in detecting localized cancers over sigmoidoscopy alone or usual care.

**Disease: Breast cancer**

Screening Methods:

*Mammography*. The most widely used breast imaging techniques are screen-film mammography and xeromammography. Preliminary results of the Canadian National Breast Screening study show first screen mammography to have a sensitivity of 69 percent, a specificity of 94 percent, a positive predictive value of 8.6 percent and a negative predictive value of 99.7 percent (13).

Screening recommendations:

*American Cancer Society*: All women should: 1) do monthly breast self-examinations, 2) have a physician perform a breast examination every 3 years between the ages of 20 and 40 years and annually thereafter, and 3) have a mammogram for baseline purposes between the ages of 35 and 40 years, every 1 to 2 years between the ages of 40 and 50 years, and annually thereafter.

*U.S. Preventive Services Task Force*: Women 50 years of age and older should be offered annual clinical breast examinations and mammography. For women at high risk, especially those with a family history of premenopausally diagnosed breast cancer in first-degree relatives, physicians may elect to recommend annual clinical breast examination and mammography beginning at an earlier age (e.g., 35 years) (314).

*Canadian Task Force*: All women should have an annual physician breast examination and mammography between the ages of 50 and 59 years.

*Epidemiologic data in support of recommendations*: Two randomized controlled trials have shown reductions in breast cancer mortality secondary to breast cancer screening. The results of the Health Insurance Plan (HIP) of Greater New York study show that yearly mammography, physician examination, and patient self-examination reduced breast cancer mortality in the study groups by 30 percent for women over 50 (268). In Sweden, a 40 percent reduction in breast cancer mortality was demonstrated among screened women ages 50 to 74 years (282). The benefits of screening for women under 50 should be determined by the National Study of Breast Cancer Screening, being conducted in Canada (results are not expected before the 1990s) (197).

**Disease: Uterine cervical cancer**

Screening Methods:

*Papanicolaou smear or PAP test*: Cells scraped from the cervical os are examined to identify cancerous and pre-cancerous cell morphology. The false negative rate associated with the PAP test is estimated to be about 30 percent (243).

Screening recommendations:

*American Cancer Society*: All women who are or have been sexually active, or who have reached age 18 should have an annual PAP test and pelvic examination. After a woman has had three or more consecutive, normal annual examinations, the PAP test may be performed less frequently at the discretion of her physician (318).

*Canadian Task Force*: Women between 18 and 35 years of age should have a PAP test annually. A PAP test should be done every five years between ages 35 and 70. No PAP tests are necessary after the age of 70 years.

*Epidemiologic data in support of recommendations*: Definitive evidence that PAP testing reduces mortality is not available. However, a body of inferential data supports the contribution of PAP testing to reduced mortality. The incidence of invasive cervical cancer is significantly lower among screened as compared to unscreened groups of women (88,170). Other evidence in support of the efficacy of PAP testing is that there are correlations between the proportion of women screened in an area and the cancer incidence and mortality rates of that area (53). Lastly, the decline in cervical cancer incidence between the mid-1950s and mid-1970s is consistent with the adoption of PAP screening (118).

**Disease: Lung cancer**

Screening methods:

*Chest x-ray, sputum cytology*: Chest x-rays and sputum cytology are used to complement one another. Chest x-rays are useful in detecting peripheral tumors, whereas sputum cytology is used to detect centrally located tumors.

Screening recommendations:

*American Cancer Society*: Specific screening for lung cancer is not indicated.

*Canadian Task Force*: Same recommendation.

*Epidemiologic data in support of recommendations*: The National Cancer Institute's (NCI) Cooperative Early Lung Cancer Detection Program that was started in the early 1970s assessed the ability to improve lung cancer detection and lower lung cancer death rates in high-risk men (smokers age 45 and older) by adding sputum cytological screening to chest x-ray screening exams. When the NCI trials commenced, it was generally accepted that yearly chest x-rays were not effective in reducing lung cancer mortality and that a large proportion of cancers detected during the trials would be detected by sputum cytology. The results of the randomized controlled trials indicate that although lung cancer detection is somewhat improved with the addition of sputum cytology screening, there is no improvement in lung cancer mortality among those subjected to both screening methods. Contrary to expectations, the majority of lung cancers were detected radiologically and not cytologically (sputum cytology alone detects 15 to 20 percent of lung cancers, almost all of which are squamous cancers with a favorable prognosis) (91,198). The evaluation of x-ray itself as a screening methodology has not been possible, because annual chest x-rays have, in many areas, become a part of routine care.

women randomized into screened and not screened study populations (268). Similar trials are underway as part of an evaluation of screening tests for colon cancer (106,320).

Although effective in reducing mortality when applied to age-appropriate populations, most available screening tests are not highly sensitive or specific. In the case of colon cancer, the Hemoccult II® kit, the most widely used commercial kit to detect occult blood in the feces (stool) is estimated to detect only 25 to 35 percent of colonic polyps (an estimated 5 percent of polyps detected would develop into colorectal cancer if not removed (2)) and 70 to 90 percent of cancers (29). Because of the relatively low sensitivity, the American Cancer Society recommends that people over 50 have sigmoidoscopy performed every year for 2 years and then every 3 years, in addition to stool occult blood testing. Although the specificity of Hemoccult II® is relatively high—97 percent for benign polyps and carcinoma—the predictive value of the test when applied to an asymptomatic population is relatively low. Fifty-two percent of positive tests represent cases of either polyps or cancer; 40 percent represent polyps, and 12 percent represent cancer (11). For every 1,000 individuals screened, there will be an estimated 20 to 60 positive results, of which about half would represent cases of polyps or cancer (figure 4-12). All positive cases need to be further evaluated by full colonoscopy or, less definitively, by flexible sigmoidoscopy or barium enema (29). Although the test for fecal occult blood is inexpensive to administer and interpret, the cost of evaluating a positive case may be as high as $1,000. In addition to being costly, the follow-up procedures are invasive and uncomfortable to the patient.

Perhaps because of its poor predictive value, physicians generally recommend stool sampling to their patients less often than published guidelines recommend. For example, despite the ACS recommendation for an annual screen for occult blood in the stool after age 50, surveys indicate that few in that age group (3 to 20 percent) have ever had one (284). Furthermore, in a 1984 survey of primary care physicians, only 48 percent reported that they followed or exceeded the ACS guideline for stool blood sampling with all patients (5). The low utilization of colorectal screening may also be explained by poor patient compliance. The screening test, which relies on stool sampling, is unacceptable to many individuals, and as many as 30 to 50 percent of patients given slides to return with stool specimens do not do so (2, 321). Both patient and physician compliance may be improved when results of the two randomized trials being conducted to assess the impact of fecal occult blood screening on mortality are completed. In addition, tests with higher sensitivity and self-tests have been developed, which may improve compliance.

Other currently available, recommended screening tests are also underutilized. Despite findings from randomized clinical trials showing reductions in mortality attributable to mammography screening for breast cancer, the procedure is underutilized according to ACS guidelines. Although the ACS recommends that women 50 and older have an annual mammogram, the 1984 survey of over 1,000 primary care physicians indicates that only 11 percent of physicians follow or exceed the ACS guidelines with all patients. In a study in which physician screening practices were compared with those expected based upon published guidelines, less than 10 percent of expected mammograms, given the age distribution of women seen in the outpatient clinic, were actually performed (322). Much of the disagreement with ACS recommendations stems from physician concerns over the exposure to x-rays associated with the procedure (5). Utilization may also be depressed due to the cost of the procedure. Mammography is relatively expensive and requires interpretation by a physician trained in radiology.

None of the widely available cancer screening methods is being directly used by insurers. These include tests for colorectal cancer, uterine/cervical cancer, and breast cancer. This may be explained by the tests' poor predictive values and ease-of-use, cost, and acceptability to the individual screened. Furthermore, as these screening tests are not widely used in medical practice, insurers are unlikely to obtain information regarding cancer screening test results when an attending physician is asked to document the applicant's medical history.

In contrast to the examples given above, despite the fact that there is no direct evidence that screening for lung cancer through chest x-rays decreases lung cancer mortality, chest x-rays continue to be widely used. Contrary to ACS guidelines, many physicians continue to conduct annual chest x-ray examinations on their patients who smoke. This may be explained by the fact that x-rays are a useful technique to detect lung cancers (as well as other diseases). Once detected, however, there are few effective treatments. This raises an important issue in screening. When screening tests are evaluated for their use by ACS and other professional groups, the focus is on the ability of

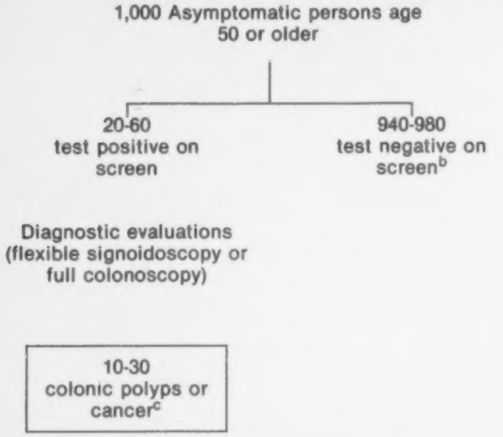

1,000 Asymptomatic persons age 50 or older
20-60 test positive on screen
940-980 test negative on screen[b]
Diagnostic evaluations (flexible signoidoscopy or full colonoscopy)
10-30 colonic polyps or cancer[c]

**Figure 4-12.—Fecal Occult Blood Screening[a]**

[a] Assumes protocol for stool sampling is followed.
[b] The American Cancer Society recommends flexible sigmoidoscopy as a complementary screening procedure. If conducted on those testing negative for blood in the stool (to 60 cm), 9% would be diagnosed with polyps and 1% with cancer.
[c] Approximately 75% of these would be colonic polyps and 25% cancer.
SOURCE: Office of Technology Assessment, 1988.

the screening test to reduce mortality. In order to achieve significant mortality reductions, the cancer must be detected at a stage in which effective therapy is possible. From the point of view of those wishing to identify latent disease, with the intent of excluding individuals from insurance or employment, tests that are effective in detecting cancers, such as chest x-rays, may be useful.

Similarly, tumor marker assays have been used to detect cancers but usually identify them at an advanced stage, when they are not amenable to treatment. Consequently, tumor markers are limited in their applications. They are used to monitor cancer therapy, to classify and stage tumors, and, in some cases, to provide prognostic information (65).

Available marker assays often fail to distinguish nonmalignant from malignant disease. As the prevalence of nonmalignant disease greatly exceeds that of malignant disease, these tests are not very predictive when used as screening tests. Sensitivity may be high for advanced cancer but is usually less than 50 percent for early or localized cancer. For example, the carcinoembryonic antigen (CEA) test, the most widely used tumor marker available, is positive in more than 80 percent of stages C and D colon cancers (advanced stages), but is positive in less than 40 percent of stage A (early stage) colon cancers. First identified as a tumor marker in 1965, CEA is now known to be associated with colon, lung, breast, and pancreatic cancers. However, CEA may also be elevated in the presence of nonmalignant diseases such as hepatitis, ulcerative colitis, gastric ulcer, and renal disease. In addition, other factors such as age or cigarette smoking may be associated with CEA elevations. When the test is applied to an asymptomatic population to detect cancer, positive tests are poorly predictive—in a population screening study of the CEA test, only 12 percent of positive tests represented CEA-associated cancers (55). Radioimmunoassay, enzyme immunoassay, and monoclonal antibody-based methods for measuring CEA are commercially available. Although test manufacturers do not recommend tumor marker assays for screening use, at least one life insurance underwriting publication has suggested that the CEA assay could be adapted and used to screen insurance applicants (103). However, because tumor markers such as CEA have not been used for screening purposes within the general medical community, they have not been used by health insurers to screen applicants.

### Future Prospects for Cancer Screening

There have been reports of tests that may be more widely applied as screening tools for cancer. One such test is based on differences found between the lipid moieties of lipoprotein particles found in the plasma of patients with cancer (called oncolipids) as compared to those without cancer (92, 328). The differences, which may represent some type of host response to malignancy, can be detected using magnetic resonance imaging (MRI) (previously referred to as nuclear magnetic resonance (NMR) spectroscopy). Patients with cancers at a range of sites (breast, gastrointestinal tract, lymph nodes, lung, bone marrow, central nervous system, and genitourinary tract) have resonance spectra that differ from both those of healthy volunteers and those with nonneoplastic illnesses, such as benign tumors, end-stage renal disease, myocardial infarction, sepsis, and diabetes mellitus. There are, however, two significant sources of false positive results—pregnant women and men with benign prostatic hyperplasia.

Although preliminary results from over 2,000 samples are promising (220), a prospective study needs to be conducted to determine how early this method can detect cancer development, and whether there is a change in result with therapy, remission, or relapse. If these studies indicate that the test may be applicable as a screening tool, the equipment, although expensive (current cost is about $500,000 each), will accommodate automated testing. More detailed analyses of the composition of all plasma lipids and the physical structures of the lipoprotein-lipid complex in various populations will improve the understanding of the underlying specific abnormality. Further research may lead to the development of a more direct assay that could be performed in laboratories without expensive MRI facilities (257).

There is a major difference in this MRI-based test and available tumor markers. Preliminary results indicate that there appears to be no correlation between the MRI spectrum observed and tumor histology or extent of disease. In contrast, tumor markers, such as CEA antigen levels, are correlated with type of tumor, histology, or tumor differentiation, as well as with the extent and sites of metastases (spread of the cancer beyond its original site). The MRI test, while potentially useful in screening for latent cancer, may not be useful in monitoring patient management. Furthermore, as cancer patients who were undergoing treatment or who had completed therapy have a range of MRI spectrum values that overlap with both normal persons and untreated cancer patients, any screening program using this technique would be expected to misclassify individuals with a recognized and successfully treated cancer.

Radioisotopes bound to antibodies specific for tumors are also being used to diagnose lung, breast, colorectal, ovarian, gastric, and pancreatic cancers. However, this *in vivo* imaging technique is not suitable as a screening technology (182).

It is widely recognized that genetics plays a role in the development of human cancers. For example, 30 to 40 percent of bilateral retinoblastoma (an eye cancer) cases are attributed to genetic factors. Approximately 10 percent of breast and colon cancers are genetic in origin (228). Guidelines have been established to help interpret family pedigrees to evaluate an individual's susceptibility to malignancy. For example, for those without cancer, the presence in the family of a first degree relative with cancers occurring in both of paired organs (not attributable to metastases), multicentric tumors, or cancer that has occurred at an atypical age or at an atypical site, suggest a genetic predisposition to cancer (228).

Genes have been identified that promote carcinogenesis when they are inappropriately activated (oncogenes) or when they are inappropriately inactivated (anti-oncogenes). For example, ras oncogenes, when activated by point mutations, appear to precede the development of some colorectal cancers (27) and adenocarcinoma of the lung (247). Analysis of the DNA from tumor cells indicates that anti-oncogenes contribute to the development of retinoblastoma and lung cancer (158). Diagnostic tests based on recombinant DNA techniques (e.g., use of oligonucleotide probes) are proving to be useful in interpreting tumor pathology. Finding oncogenes in cancerous tissues is helping physicians decide how to manage patients with breast, lung, and cervical cancers, and neuroblastoma. Patients with many copies of an oncogene in their cancerous tissues appear to have a poorer prognosis than patients without oncogene amplification. However, this does not hold true for all tumors. Thus, some high risk cancer patients may be identified for particularly aggressive anti-cancer treatments. While presently a useful tool in cancer patient diagnosis and management, applications in screening have not yet been developed.

Investigators are searching for genetic markers of susceptibility to cancer. Using blood samples from individuals whose families are known to be at risk of developing cancer, one biotechnology company, with NCI support, is looking for the presence of DNA markers for defective genes associated with lung, breast, and colon cancer (185). Another biotechnology company has developed DNA probes to detect gene rearrangements associated with lymphoid malignancies and is also evaluating a test for human papilloma virus, a virus associated with a high risk of cervial cancer in women (182).

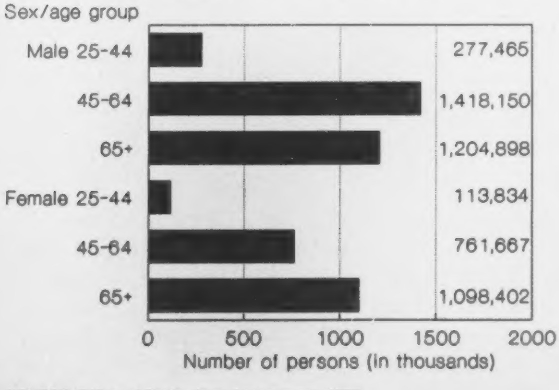
## Testing for Heart Disease

### Introduction

The prevalence of coronary heart disease (CHD, also called coronary artery disease or CAD) among those between the ages of 25-44 is estimated at 0.7 percent for males and 0.3 percent for females (8, 293). Figure 4-13 summarizes the prevalence of heart disease among persons age 25 or older. For males 15-44 years old, heart disease is the second leading cause of hospitalization, with an estimated 3.3 discharges per 1,000 males in that age group (295). Approximately 13 percent of heart attacks occur among males between the ages of 29-44 (8).

CHD age-specific mortality has been declining. Between 1972 and 1984 it declined by about 34 percent (7). Most of the decline has been attributed to changes in lifestyle, such as lowering dietary fat intake and stopping smoking. Improvements in managing hypertension and medical and surgical interventions for those with CHD have also contributed to the decline (108). Despite this decline in age-specific mortality, some predict that deaths, sickness, and costs associated with CHD could increase by more than 40 percent over the next quarter century. These increases are, in part, attributable to demographic trends and to increases in costs associated with CHD diagnostic technologies and treatments (301).

**Figure 4-13.-Estimated Number of Persons With Coronary Heart Disease, 1985**



SOURCE: Office of Technology Assessment, 1988.

### Electrocardiogram (EKG) and Exercise Stress Testing

The electrocardiogram (EKG) is a record of the electrical activity of the heart and is used to detect abnormal cardiac rhythm and heart muscle damage. The EKG is not a sensitive test for presymptomatic heart disease (93). Exercise EKGs (also called stress EKGs) are more sensitive than resting EKGs. However, in a population at low risk for heart disease, the predictive value is poor. In a population with a prevalence of coronary disease of 1 percent, a person with a positive exercise EKG would have only a 7 percent chance of having CHD, while a person with a negative test would have a 0.3 percent chance of having CHD. While the relative risk is high (23 times the lower risk), the absolute risk is low (134). Exercise EKGs may be useful in evaluating a high-risk person who wishes to engage in strenuous physical activity, but it is a relatively expensive test that also carries a small, but definite risk (stress EKGs result in approximately 3 deaths per 10,000 patients).

An alternative to exercise EKGs will soon be marketed (186). A device called the ischemia scan uses 30 electrodes to measure approximately 500 heart beats for evaluation. The heart beats are analyzed by a high-speed array processing microcomputer, and the results indicate the overall amount of ischemic tissue (insufficient oxygen due to poor blood supply) present. The test is reportedly able to provide earlier detection of heart damage than EKGs, because it can test for as little as five grams of ischemic tissue, compared to an estimated 100 grams of tissue required to provide a positive reading with EKGs. The sensitivity is also reported to be higher than that of EKGs (90 percent versus 70 percent). Furthermore, the ischemia scan involves no risk of death, since no stress testing is involved. The scan's projected cost is comparable to that of the EKG (approximately $200). Additional testing is being conducted to evaluate the use of the scan among asymptomatic patients.

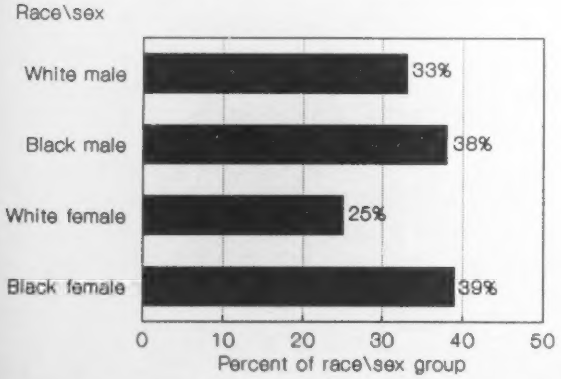
### Coronary Heart Disease Risk Factors

Risk of future CHD disease can be determined by evaluating CHD risk factors singly or in combination. The three main predictors of CHD other than age and sex are hypertension, hypercholesterolemia, and cigarette smoking (181).

**Hypertension.**—Hypertension is a risk factor for heart attack, renal failure, stroke, and a number of other health problems (93). Blood pressure measurements are noninvasive, can be performed by a nonphysician, and are often performed during routine medical visits. According to medical practice guidelines, blood pressure should be recorded on any visit to a physician, not just at periodic health examinations (39). When hypertension is defined as a diastolic pressure greater than 95 mmHg, 38 percent of black males, 39 percent of black females, 33 percent of white males, and 25 percent of white females ages 18 to 74 are affected (figure 4-14). According to prospective studies, a 45-year-old hypertensive (systolic BP=195 mmHg) male without other risk factors is at about twice the risk for CHD than a similar but normotensive male (7).

Although hypertension is a known risk factor for CHD, treatment of hypertension is not clearly associated with a decline in CHD deaths. One epidemiologic study (the Hypertension Detection and Follow-up Program) showed a 20 percent reduction in CHD deaths with control of hypertension, but other studies have not shown significant reductions of complications from CHD associated with hypertension control (93).

**Figure 4-14.-Hypertension Prevalence by Sex and Race, U.S. Adults Age 18-74**[a]



[a] Hypertensives are defined as persons with a systolic level greater than or equal to 140 and/or a diastolic level of greater than or equal to 90 or who report using anti-hypertensive medication.

SOURCE: American Heart Association, "1988 Heart Facts," Dallas, TX, 1988.

**Hypercholesterolemia.**—Epidemiologic studies have shown a close relationship between serum total cholesterol and the subsequent development of CHD (154). The risk is not confined to those with extremely high values. Instead, the risk rises continuously with cholesterol level (273). An expert panel convened by the National Heart, Lung and Blood Institute has recently issued a report (303) setting a new standard for measuring cholesterol in adults over age 20. Previously, cholesterol levels above either the 90th or 95th percentile for age had been considered abnormal. The new classification specifies three total cholesterol ranges, characterizing those with high levels (240 mg/dl or more), borderline levels (200-239 mg/dl), and desirable levels (below 200 mg/dl).

As measurements of cholesterol, lipoproteins, and the protein components of lipoproteins are used in the evaluation of CHD risk, a brief description of cholesterol and its metabolism is in order.

Cholesterol is essential to the synthesis of cell membranes, steroid hormones (e.g., testosterone, estrogen), and is a component of bile (digestive juices). Cholesterol found in the plasma does not occur in a free state but is "packaged" and transported in the blood by plasma lipoproteins. Lipoprotein receptors are located on cell surfaces. Through these receptors, the cell binds to the lipoprotein containing the transported cholesterol. The cell then engulfs the lipoprotein (endocytosis), and the cholesterol is "carried" into the cell. This process, when functioning normally, keeps the blood concentration of cholesterol low enough to prevent the buildup of atherosclerotic plaques.

The plasma lipoproteins that carry cholesterol can be distinguished by their density. The three most important cholesterol-bearing lipoproteins are very low density lipoproteins (VLDL), low density lipoproteins (LDL), and high density lipoproteins (HDL). Lipoproteins differ in density because they consist of different proportions of lipids (triglycerides and cholesterol). The LDL fraction carries 70 percent of serum cholesterol, compared to 20 percent carried by HDL (245). The protein components of lipoproteins are called apolipoproteins (13 major human apolipoproteins, A through H, have been described (32)). Apolipoprotein A (apo A) is the protein component of HDL, while apolipoprotein B (apo B) is the major protein component of LDL. These proteins exist in various forms. For example, both apo A and apo B exist primarily in two forms (apo A-I and A-II; apo B-100 and B-48). Changes in serum levels of apo A and apo B correlate with changes in HDL and LDL, respectively.

Elevations in total serum cholesterol, LDL, and apo B are risk factors for atherosclerosis and CHD. Conversely, low levels of HDL and apo A are associated with CHD (43). Evaluations of the relative utility of plasma levels of cholesterol, triglycerides, HDL-cholesterol, and apolipoproteins in distinguishing healthy men from those with CHD have shown that levels of apo A-I, A-II and B are the best discriminators. In one study, 75 percent of men who were either normal or had significant coronary artery disease could be correctly identified using age and apo A-I, apo A-II, and apo B levels (160).

Much information about CHD risks has been gleaned from the Framingham prospective study, in which risk factors and heart disease status have been monitored for a cohort of initially asymptomatic individuals for more than 20 years. This study revealed that most cases of CHD arise from those in the population with only modest elevations of serum cholesterol. The average cholesterol level among those under age 50 who later developed CHD was only 244 mg/dl (154). Although high (NHLBI defines abnormally high as 240 mg/dl or more), the fact that 244 mg/dl is the average indicates that many had levels in the borderline or normal range.

The strength of the association between cholesterol levels and CHD varies according to age and the presence of other CHD risk factors. The association declines with advanced age. In fact, total cholesterol is no longer predictive of CHD among men over age 65. The same cholesterol level may confer a different risk according to the presence of other risk factors (e.g., smoking, hypertension, abnormal glucose tolerance test). The relative risk of CHD developing within 18 years for a 35-year-old male with one risk factor—high cholesterol (total cholesterol of 335 mg/dl)—as compared to a 35-year-old male with no risk factors, is 3.9. The relative risk increases to 23.2 when both cholesterol and blood pressure (BP) are elevated (systolic BP=195 mmHg) and to 60.2 when all risk factors are present (i.e., elevated cholesterol, elevated BP, smoking, abnormal glucose tolerance test, left ventricular hypertrophy) (154).

There has been concern over the accuracy of the estimated 100 million cholesterol tests performed yearly. A 1985 study of the reliability of cholesterol testing conducted by the College of American Pathologists (CAP) showed that many tests being conducted are inaccurate. As a part of their evaluation, about 5,000 of the nation's top laboratories were sent identical samples. Nearly half of the results were, according to experts, unacceptable (26). In response to these problems, CAP has recently made available "certified reference materials" in the form of freeze-dried human blood serum. The freeze-dried samples can be reconstituted and tested along with other samples. These reference materials will help to ensure that instrumentation is properly calibrated. CAP also conducts a laboratory proficiency survey program on a quarterly basis (50).

To achieve accuracy and reliability in cholesterol testing, a NIH panel (Laboratory Standardization Panel) has recommended that uniform cholesterol cutoff points be adopted to identify adults at high risk for CHD and that cholesterol measurements be standardized and that deviations from true cholesterol values not exceed 5 percent (within 5 years the deviation should not exceed 3 percent) (319).

Automated laboratory desk-top analyzers hold promise in facilitating mass-screening efforts. These new analyzers require only a small amount of blood per test and are inexpensive (less than $3 per screen) (112). Eleven lipid research clinics have evaluated a rapid, desk-top analyzer. The assay was applied to nearly 13,000 people at schools, work sites, shopping malls, and other locations. The analyzer determines cholesterol levels within 3 minutes, giving results that vary about 1 to 4 percent from rigorous, standardized laboratory methods (78). Despite these favorable results, there is concern that results may not be accurate if machines are not maintained, as may be the case in nonmedical settings. The NIH Laboratory Standardization Panel has not recommended the use of portable chemistry analyzers to measure cholesterol, arguing that their accuracy has not been thoroughly evaluated and that staff are inadequately trained to use them.

Although widespread screening is now being encouraged by the NIH National Cholesterol Education Program, physicians appear to be reluctant to participate (263). This may in part be explained by some uncertainty regarding the beneficial effects of lowering cholesterol levels. Hypercholesterolemia is a recognized risk factor for CHD, and dietary and drug-induced reductions in serum cholesterol have been associated with fewer new cases of CHD among asymptomatic men with high levels (225). The Lipid Research Clinics Coronary Primary Prevention Trial, for example, showed that lowering LDL-cholesterol by 12.6 percent with medications was associated with a 19 percent reduction in CHD. However, in all of the studies, the decrease in CHD was offset by an increase in non-cardiovascular mortality, and in several of the studies, there were no differences in total mortality (225).

With continued medical education, physician screening practices may change. According to a 1986 national survey of physicians, 64 percent of physicians thought that reducing high blood cholesterol levels would have a large effect on heart disease, up considerably from 39 percent in 1983 (261). There is evidence that more individuals are having their cholesterol measured. According to a national survey, 46 percent of adults reported that they had their cholesterol level checked in 1986, compared to 35 percent in 1983 (262).

When diet and exercise are ineffective in lowering cholesterol, medication may be effective. In clinical studies, a recently approved drug (lovastatin) reduced total cholesterol by 18 to 34 percent. The drug is the first of a new class of products that inhibit the enzyme regulating the production of cholesterol (10). Other classes of available cholesterol-lowering medications include bile acid sequestering resins, nicotinic acid, and fibric acid compounds.

While an interaction of environmental and genetic factors is known to contribute to the development of atherosclerosis, an estimated 5 to 10 percent of the population is strongly genetically predisposed to the development of atherosclerosis, while another 5 to 10 percent is strongly genetically resistant. For the remaining 80 to 90 percent of individuals, both genetic and environmental factors determine who develops atherosclerosis (130).

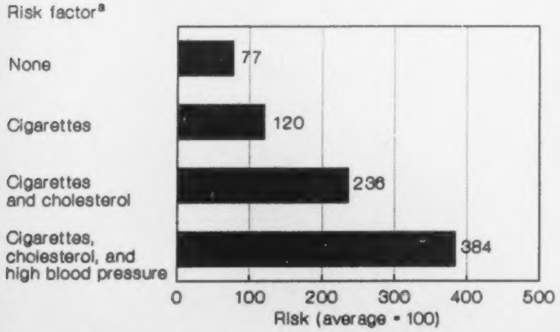
Familial hypercholesterolemia (FH) is an autosomal dominant inherited disease (i.e., the offspring of affected individuals have a 50 percent chance of inheriting the FH gene) and occurs with a frequency of about 1 in 500 (33). FH is caused by inherited defects in the gene encoding for the LDL receptor. These defects (at least 12 different mutations have been identified) disrupt the normal control of cholesterol metabolism (135). LDL is very elevated in those with FH and results in premature atherosclerosis (21). For those with one of the defective genes, myocardial infarction frequently occurs by age 30 to 40, and death usually occurs before age 60 (33). Treatment for FH is available, but it is necessary to institute it early to prevent the vascular complications of the disease. Examining those with a family history of early CHD is worthwhile. In fact, the American Heart Association (AHA) recommends that physicians contact first-degree relatives of all patients who have developed any clinical features of CHD under the age of about 50 (7) . However, this will not have a large impact on overall incidence. Among those under age 60 who suffer myocardial infarctions, only about 5 percent represent FH, and approximately 10 to 20 percent of those with one defective gene do not have myocardial infarctions until they are 80 to 90 years old, despite pronounced hypercholesterolemia from birth (33) .

**Calculation of Risk Profiles.**—In terms of recommended CHD screening practices, physicians have generally been advised to screen for and reduce risk factors, including tobacco use, elevated serum cholesterol, and hypertension. Routine

EKGs are not indicated as a screening test (93). The Canadian Task Force on the Periodic Health Exam states that no screening is recommended for CHD, although screening for hypertension is recommended for other reasons.

Based on the longitudinal Framingham Study, estimates of individual risks for heart disease have been calculated according to demographic, behavioral, and health characteristics. Physicians can apply the results of the Framingham Study to their evaluation of individual asymptomatic adult patients. Risk scores are calculated based on a patient's age, sex, systolic blood pressure, serum cholesterol, presence of left ventricular hypertrophy (as determined by EKG), smoking status, and presence of sugar in the urine (154). Figure 4-15 summarizes relative risks when cigarettes, high cholesterol, and high blood pressure are present. While useful, these calculations will identify many who will develop heart disease as low risk, and predict others to be at high risk who will remain disease-free. In fact, only about half the risk of CHD can be accounted for by known risk factors. For example, while both hypertension and hypercholesterolemia are recognized risk factors for CHD, two-thirds of healthy adult men ages 40-55 who are above the 80th centile for elevated cholesterol levels and blood pressure will remain well over during the subsequent 25 years (235). Therefore, although the presence of these risk factors raises one's relative risk, the absolute risk remains low.

**Figure 4-15.-The Danger of Heart Attack Increases With the Number of Risk Factors Present**



[a] The dangers of heart attack increase with the number of risk factors present. For purposes of illustration, this chart uses an abnormal blood pressure level of 180 systolic and a cholesterol level of 310 in a 45 year old man.

SOURCE: American Heart Association, "1987 Heart Facts," Dallas, TX, 1987.

**DNA-based Tests for Heart Disease.**—Analyses of associations between genetic variations (polymorphisms) and the occurrence of cardiovascular disease are one of the promising areas of research relating to the development of predictive tests for heart disease. Currently, disease risk assessment includes measurement of risk factors such as elevations of plasma lipids and blood pressure. Genetic tests may further refine risk assessment and can be applied early in life before signs of disease become apparent. The development of DNA predictive tests for non-infectious disorders, however, is in its infancy, and many hurdles must be overcome before they become a part of routine care. To date, several associations have been documented between specific genetic polymorphisms and disease. These initial studies will need to be replicated and prospective studies conducted before predictive tests will have clinical utility.

Genetic polymorphisms in the region of the three apolipoprotein genes (apolipoproteins A-I, A-IV, and C-III) clustered on chromosome 11 have been associated with CHD and lipoprotein abnormalities (130). Apolipoprotein A-I is the principal protein constituent of HDL-cholesterol and may promote removal of cholesterol from the arterial wall. An HDL-cholesterol level below the 10th percentile for age and sex has been observed in 60 percent of patients with CHD under age 60 (226).

A restriction fragment length polymorphism (RFLP) (see section on genetic tests for a description of RFLPs) flanking the apo A-1 gene has been used to study the association of early CHD with specific genetic variants. In one study, a 3.3 kb (kilobase) band appeared in 4.1 percent of randomly selected control subjects and 3.3 percent of 30 subjects with no angiographic evidence of CHD. In contrast, 32 percent of 88 patients with severe CHD before the age of 60 had the 3.3 kb band. The authors concluded that the relative risk of CHD associated with the presence of the 3.3-kb band is at least 10 (226). To put this relative risk in perspective, the relative risk of CHD developing within 18 years for a 35-year-old male with only high cholesterol (total cholesterol of 335) as a risk factor is estimated to be 3.9 (154).

Although significant associations between the presence of genetic variation and disease and/or lipid abnormalities have been identified in some studies, these have not been predictive of disease in all studies. This is illustrated by looking at recent work relating to the association of DNA polymorphisms within the coding sequence of the apo B gene (located on chromosome 2) with lipid abnormalities (164) and myocardial infarction (MI) (131). As discussed earlier, high plasma apo B levels (the protein associated with LDL) are associated with an increased prevalence of atherosclerosis. Some investigators have found specific RFLPs associated with altered plasma LDL cholesterol levels. In one study, subjects with a specific apo B gene RFLP had triglyceride, cholesterol, and apo B levels of 36, 8, and 10 percent, respectively, higher than those without the restriction site (164). However, the presence of the restriction site is common. In the study group of 83 males ages 40 to 64 (enrolled in a prospective heart disease study), 60 (72 percent) had the allele (X1) associated with higher plasma lipid levels. Furthermore, despite the observed differences in plasma lipids, the 95 percent confidence limits associated with the mean levels of cholesterol and triglycerides for each group overlapped (table 4-11), indicating that there was no statistically significant difference between the groups. Given the frequency of the X1 allele and the lack of a strong association between its presence and altered lipid levels, it does not appear as a likely disease marker.

Other investigators have studied this same polymorphism of the apo B gene and found it to be associated with MI but not with altered levels of LDL-cholesterol or apo B (131). When cases with MIs were compared with matched controls, there were significant differences between the groups with and without the XbaI restriction site. Myocardial infarction cases were more likely to have the 8.6 fragment (designated as X2 above) than controls (88 percent versus 74 percent). As these investigators did not find significant differences between the allele associated with the 8.6 fragment and LDL-cholesterol or apo B levels, they postulate that regions of the apolipoprotein B gene other than the LDL receptor binding region represent independent risk factors for MI (131).

In addition to the XbaI allele, these investigators found two other alleles that were more common among MI patients. However, none of the alleles were very predictive of MI (odds of disease, given the presence of associated markers, were less than 1.8). As the investigators point out, however, finding differences larger than these would have been surprising, given the complexity of the atherosclerotic process. A very large difference in allele frequency between cases and controls would imply that variation at one particular genetic locus is associated with the development of MI in a large fraction of cases, and this is unlikely. Further studies in which cases are selected for a clinically defined subset of persons experiencing an MI may show a stronger association. In addition, prospective studies will need to be undertaken to evaluate the predictive value of the presence of these genetic variants. It is unlikely

**Table 4-11.—Serum Cholesterol and Lipid Concentrations in 83 Subjects by RFLP Genotype (XbaI Restriction Endonuclease)**

| | Genotype[a] | | |
|---|---|---|---|
| | X1X1 (n=27) | X1X2 (n=33) | X2X2 (n=23) |
| Cholesterol (mmol/l)[b] ....... | 5.14 (3.89-6.80) | 5.19 (3.73-7.23) | 4.79 (3.75-6.12) |
| Triglyceride (mmol/l)[b] ....... | 1.60 (0.67-3.84) | 1.59 (0.46-5.60) | 1.17 (0.46-2.96) |
| Apo B (mg/dl)[c] ............. | 85.1 +/−29.6 | 86.2 +/−51.4 | 76.7 +/−35.4 |

[a] Genotype X1X1 associated with one 5.0 kb fragment.
Genotype X1X2 associated with two fragments, 5.0 kb/8.6 kb.
Genotype X2X2 associated with one 8.6 kb fragment.

[b] Log data analyzed; geometric mean and approximate 95% range is given.

[c] Mean plus or minus the standard deviation.

SOURCE: Office of Technology Assessment, adapted from A. Law, L.M. Powell, H. Brunt, et al., "Common DNA Polymorphism Within Coding Sequence of Apolipoprotein B Gene Associated With Altered Lipid Levels," *Lancet* 1(8493):1301-1303, June 7, 1986.

that DNA markers will replace the need for determining quantitative plasma lipoprotein or apolipoprotein levels. Instead, DNA markers will probably be used with plasma lipoprotein and apolipoprotein levels to enhance the ability to diagnose susceptibility to develop atherosclerosis (130).

## Testing for Alcoholism

Alcoholism affects an estimated 10 million Americans. Among males, the prevalence of alcohol abuse or dependence is estimated to be between 8 and 10 percent and among women, between 1 and 2 percent (241). Alcoholism, the result of tolerance and physical dependence on alcohol following long-term use, was recognized as a disease in 1956 (122). The health consequences of alcoholism may include liver disease, nutritional deficiency, brain dysfunction, and an increased susceptibility to a number of other chronic disorders, such as diabetes and heart disease. Furthermore, motor vehicle accidents, industrial accidents, and family violence occur in association with alcohol use, in part as a consequence of alcohol-related sensory-motor and cognitive impairment. With such wide-ranging physiologic effects it is not surprising that alcohol is estimated to play a role in approximately 10 percent of all deaths in the United States (73).

Several methods have been employed to improve the clinician's ability to recognize alcoholism, because alcoholism is often not diagnosed during physician-patient encounters. These methods include alcoholism questionnaires, biological markers of alcohol consumption, and tests to detect the early effects of alcohol use. Future methods may include markers of vulnerability to alcoholism (e.g., genetic predisposition) and predictors of who among those who drink will develop serious health consequences of alcohol use (e.g., cirrhosis of the liver) (240).

The two most widely used questionnaires are the CAGE questionnaire (an acronym derived from four questions asked) (Box 4-B) and the Michigan Alcoholism Screening Test (MAST). The MAST questionnaire contains 24 yes-no items regarding drinking behavior and problems associated with excessive drinking. In contrast to the CAGE questionnaire, when alcoholism is detected, MAST provides some information about the severity of the problem. As screening devices, the two questionnaires are comparable in accuracy. When evaluated in outpatient settings their sensitivity ranges from 55 to 97 percent, while specificity ranges from 79 to 96 percent (57,122).

### Box 4-B.—CAGE Alcoholism Questionnaire

The CAGE Questionnaire:

1. Have you ever felt you ought to **C**ut down on your drinking?
2. Have people **A**nnoyed you by criticizing your drinking?
3. Have you ever felt bad or **G**uilty about your drinking?
4. Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (**E**ye opener)?

SOURCE: Hays, J.T. and Spickard, W.A., "Alcoholism: Early Diagnosis and Intervention," *J. Gen. Intern. Med.*, 2: 420-427, November/December 1987.

Laboratory indicators of alcohol consumption include the blood alcohol concentration (BAC) and elevated levels of the liver enzymes gamma-glutamyl transpeptidase and glutamic-oxaloacetic transaminase. BAC may be the most under-used biochemical test in screening for alcoholism (162). The level of alcohol in the blood may indicate high alcohol consumption and provide evidence of tolerance to alcohol. However, recent consumption may not be detected, because alcohol is usually cleared from the system within 24 hours (241).

Serum levels of gamma-glutamyl transpeptidase (SGGT) are not accurate indicators of alcohol use, as there is little correlation between alcohol intake and levels of SGGT. Among known groups of alcoholics, less than one-third have elevated SGGT levels. Serum levels of glutamic-oxaloacetic transaminase (SGOT) are even less sensitive indicators, because elevation in SGOT occurs only with more severe liver damage. Taken singly, these tests are not accurate predictors of alcoholism, but some investigators have analyzed combinations of tests and found them useful. One group of investigators has used statistical techniques (quadratic discriminate analysis) to interpret the findings of a battery of 25 commonly ordered laboratory tests (complete blood count and SMA-18) to identify alcoholics. This technique has successfully distinguished between those with biopsy-verified alcohol and nonalcoholic liver disease (252). However, this statistical technique has not been evaluated for its ability to identify those with preclinical or early-stage alcoholism.

One potentially promising method to assess alcohol consumption relies on the finding that alcohol modifies hemoglobin. Hemoglobin-carrying red blood cells live for about 120 days and can be sorted by age (110). By studying alcohol-modified hemoglobin in age-stratified red blood cells, it may be possible to assess the nature and pattern of alcohol use over the previous three-month period (256).

Early physical signs and symptoms of alcoholism may include: gastrointestinal (GI) problems (e.g., early morning vomiting, chronic diarrhea, gastritis, GI bleeding); hypertension or arrhythmias and palpitations in a patient without known heart disease; sleep disturbances; and sexual dysfunction (122).

Many studies have compared the relative effectiveness of laboratory indicators versus questionnaires as alcoholism screening tools. In almost all cases, both the CAGE and the MAST questionnaires have been shown to be superior to any of the laboratory markers used to identify alcoholics (122). Furthermore, the CAGE questionnaire has been shown to be an effective tool for detecting both alcohol-dependent and alcohol-abusing patients (34).

Recent preliminary research on another biologic-marker for alcoholism shows promise (inhibition of monoamine oxidase by ethanol and stimulation of platelet adenylate cyclase activity) (281). These markers correctly categorized 75 percent of alcoholics and 73 percent of nonalcoholic controls. Furthermore, the tests were able to detect abnormalities in alcoholics who had abstained from alcohol for as long as 23 days. If this biologic marker is a measure of the underlying basis of alcoholism (there is evidence of genetic susceptibility to alcoholism) rather than a measure of the effects of alcohol consumption, primary prevention would become possible, because susceptible individuals could be identified and counseled before they began drinking. Further research will be necessary to clarify whether this marker proves to be useful.

## SELF-TESTING/HOME DIAGNOSTIC PRODUCTS

### The Availability of Home Diagnostic Products

#### Introduction

There are now approximately 60 do-it-yourself kits available to detect a variety of conditions, ranging from pregnancy and ovulation to blood in the stool. These products have been popularized through books and journals. One such book describes how to correctly obtain a urine and blood sample at home and how to conduct and interpret more than 160 screening tests, including tests for diabetes, hypertension, sickle cell disease/trait, gonorrhea, and alcoholism. The authors do not suggest home medical testing as an alternative to physician-ordered testing but rather as an adjunct to it (234).

Self-administered tests may be valuable in identifying signs of latent disease. Asymptomatic individuals can test themselves for hypertension and colon and breast cancer using over-the-counter (OTC) testing products. Prompt medical attention at an early stage of disease may prevent or ameliorate the course of the disease. Those with symptoms of illness may screen themselves for strep throat infections, urinary tract infections, and some kinds of sexually transmitted disease.

The largest market for home testing has been in the area of therapeutic monitoring. Diabetics monitor their insulin control through urine and blood glucose tests, and some patients with heart disease monitor drug levels. Market forecasters predict substantial growth in the home testing market (table 4-12). This may be attributed in part to the aging of the American public. By the year 2000, an estimated 13 percent of the population will be aged 65 or older (292). Given the frequency of those 65 or older who have at least one chronic condition, these products, especially those used to monitor therapeutic control, may be widely used.

The number of home testing products has increased largely as a result of technological advances that have simplified tests. For example, accurate, easy-to-use, enzyme-linked immunoassays have shifted testing away from clinical labs to physicians' offices. Many of the tests now available to the consumer are the same as those used by physicians (95).

While some argue that home testing may facilitate early treatment and therefore better health outcomes, others are concerned that consumers will misuse or misinterpret test results and delay or not seek needed medical care. There is also concern that the widespread use of tests with inherent false positive results may lead to unnecessary physician visits and expensive follow-up evaluations. While physicians believe that patient self-diagnosis is on the rise, their opinion on self testing is divided. Physicians favor urine glucose/ketone, blood glucose, and occult fecal blood testing, but are generally opposed to self-diagnosis of urinary tract infections, sexually-transmitted diseases and breast cancer (via thermography) (23).

An extension of home testing is the development of self-service laboratories, where individuals may order a variety of clinical tests without the participation of a physician. For example, a California-based, private laboratory, offers 36 different tests directly to the public. Included are tests for early detection of disease/infection (e.g., HIV antibody testing), indicators of exposure to toxic industrial substances, nutritional and allergy profiles, drug testing, and standard blood and urine workups (e.g., glucose, cholesterol, and triglyceride levels). The laboratory is run by a physician who refers clients to a physician if warranted by the test results (28).

Some laboratories have sold kits in which the consumer collects a specimen (usually blood by the fingerstick method) and sends it to the lab for analysis. Even though the test kit that is sold to the consumer contains FDA-approved components (e.g., lances, swabs, blood collection tubes) manufacturers of such kits are required to notify the FDA prior to selling the kits. Manufacturers of such kits have withdrawn them from the market and have applied to the FDA for their ap-

**Table 4-12.—Summary of Market Research Reports on Home Testing Products**

| Market researcher/product | Year | Market value (millions) | Year | Market value (millions) |
|---|---|---|---|---|
| Find-SVP | | | | |
| **Entire market** | **1986** | **$668** | **1995** | **$2,200** |
| Fecal occult kits | 1986 | $ 33 | 1995 | $ 136 |
| Breast cancer screening kit | 1986 | $ 1 | 1995 | $ 7 |
| Blood pressure monitoring | 1983 | $ 69 | 1986 | $ 100 |
| Packaged Facts | | | | |
| **Entire market** | **1987** | **$515** | **1992** | **$1,400** |
| Biomedical Business International | | | | |
| **Entire market** | **1986** | **$432** | **1990** | **$1,200** |
| Blood glucose test | 1986 | $205 | 1990 | $ 445 |
| Blood pressure monitoring | 1986 | $112 | 1990 | $ 211 |
| Urine glucose | 1986 | $ 19 | 1990 | $ 15 |
| Fecal occult kits | 1986 | $ 3 | 1990 | $ 9 |
| Business Communications Co. | | | | |
| **Entire market** | | | **1990** | **$2,500** |
| Frost and Sullivan | | | | |
| **Entire market** | **1984** | **$348** | **1989** | **$ 736** |

SOURCE: Office of Technology Assessment, 1988.

proval. As of early 1988, such test kits have not been approved by the FDA.

### The Market for Home Tests

Estimates of the market value for home diagnostic products by 1989-1995 vary from $736 million to $2.5 billion (see table 4-12). The projections vary in part because of differences in what is considered a home test. Some estimates include the projected sales of thermometers and "home care products" such as condoms. Earlier projections that sales of self-testing products would exceed $1 billion by the mid-1980s have not been realized. Although actively promoted, home pregnancy tests are used by only 7 percent of women of child-bearing age, and only 9 percent of all households have blood pressure kits (23). An estimated 20 percent of insulin-dependent diabetics use blood glucose kits (22). Among the barriers to market penetration are that many consumers do not want to know about their disease; rely on their physicians for tests; are unwilling to pay for OTC testing products; are intimidated by testing technology; and lack knowledge of health problems that would enable them to consider self-testing (23). Self-testing products are used by the better-educated and higher-income consumer (77). Some of these barriers may be overcome by aggressive marketing. Retail outlets for tests include drug stores, physician offices, HMOs, nursing homes, health clubs, and businesses.

### Accuracy and Reliability of Home Tests

The major concern regarding home diagnostic tests is that false negative test results may lead to a delay in treatment and that false positive test results may lead to unnecessary follow-up testing and emotional stress. Erroneous results may occur through test misuse or because of inherent limitations of the tests themselves.

There are two reporting systems established to identify problems associated with medical devices, including home diagnostics. First, health care practitioners can, on a voluntary basis, report problems to The Medical Device & Laboratory Product Problem Reporting Program, which is administered by the United States Pharmacopoeia Convention, Inc. and funded by the FDA. The program is interested in receiving information about design defects, device malfunctions, improper packaging, questionable sterility, and inadequate labeling or instructions (18).

A second reporting system, the FDA's Medical Device Reporting (MDR) system, includes reports of device-related injuries, deaths, and device malfunctions that could lead to injury or death. Manufacturers are required to report such experiences to the MDR system. Approximately 1,600 reports of injuries and malfunctions have been logged with the MDR system for home glucose screens alone (from December, 1984 to June, 1987), mostly due to improper use (63). The FDA is evaluating the source of the problems, and if the patient education process is implicated, manufacturers may be required to provide clearer device labeling and less complex training literature (64).

The FDA, in recognition of potential problems associated with home test kits, is in the process of issuing guidelines to the manufacturers of such products. In the proposed guidelines, FDA suggests that manufacturers demonstrate that home test kits show "probable health benefits" and that they can be operated easily. Firms are also advised to prove that there are benefits of performing the test at home instead of having the test performed by health care professionals. Manufacturers will also be required to document the impact of a false positive or false negative test result to the user or to society (e.g., delay in seeking medical care). Companies will be required to submit data showing that home tests "perform as well as their professional-use *in vitro* diagnostic equivalents . . . [and] should be designed . . . to ensure that performance will not be appreciably affected by anticipated variation in user technique" (63). Most home test kits will be approved by the relatively short premarket notification process. The currently available FDA-approved HIV tests are licensed for blood bank and lab usage, but not for home or in-office use.

### Conclusion

Currently, there are few home diagnostic tests that would lead an insurer to expand their use of diagnostic testing. However, with improvements in technology, a wider variety of home diagnostics may be available. These include tests for disease susceptibility such as HIV infection (see AIDS section), and colon cancer (improved occult fecal blood tests). Genetic probe tests suitable for home use will not be available in the near future (see genetic testing section). However, if such tests are available and they are widely used, insurers may consider expanding their testing efforts to avoid adverse selection.

# Appendixes

## Appendix A

# The Uninsured, Underinsured, and People With AIDS

## Introduction

In 1986, an estimated 13.3 to 15.7 percent of the U.S. population did not have either private or public health insurance (tables 1-1 and A-1).[1] Furthermore, in 1984 people with inadequate health insurance coverage were estimated to be between 8 and 26 percent of the under 65-year-old population (87). It is highly likely that a large number of people with AIDS are underinsured under some definitions of inadequate health insurance coverage. Thus, the impact of AIDS on the uninsured and underinsured populations must be considered in analyses of options for decreasing the number of people without health insurance (31.0 million to 37.2 million in 1986) and helping those who are underinsured.

Definitions of the terms "uninsured" and "underinsured" have a large influence on the size and characteristics of the populations in question. In the case of defining the uninsured population, there is general agreement that the uninsured are people who lack any form of private or public health insurance. However, the definition of uninsured becomes complicated if a time dimension is included. Is the uninsured population comprised only of people who lack health insurance over a period of time (e.g., a year)? Or is the uninsured population composed of anyone who has lacked health insurance during a period of time but not necessarily during the entire period?

**Table A-1.—Geographical Distribution of the Uninsured: Number and Percentage of Population (all ages) by Census Division, 1986**

| Division | Number of uninsured | Percent of each region's population that is uninsured |
|---|---|---|
| New England | 1,348,000 | 10.7 |
| Middle Atlantic | 4,712,000 | 12.8 |
| South Atlantic | 6,467,000 | 16.3 |
| East North Central | 5,185,000 | 12.5 |
| East South Central | 2,827,000 | 19.1 |
| West North Central | 2,213,000 | 12.8 |
| West South Central | 5,634,000 | 21.5 |
| Mountain | 2,315,000 | 18.1 |
| Pacific | 6,478,000 | 18.5 |
| Total United States | 37,180,000 | 15.7 |

SOURCE: U.S. Department of Commerce, Bureau of the Census, "Current Population Survey," unpublished data, March 1986.

The most widely used estimate of the number of uninsured has relied on the point-in-time definition. The reason for this is grounded in pragmatic considerations. Data on the uninsured over the course of a year come primarily from the National Medical Care Expenditure Survey (NMCES) and the National Medical Care Utilization and Expenditure Survey (NMCUES). The NMCES was conducted in 1977, and the NMCUES was conducted in 1980. Neither of these surveys can account for the effects of the 1981-82 economic recession and the changes in Medicaid eligibility criteria since 1980 on the total of uninsured people. In the years since NMCUES was conducted, the size and characteristics of the uninsured population have been estimated primarily from the Health Interview Survey (HIS) and the March supplement to the Current Population Survey (CPS).[2]

Because the CPS and HIS have been used to estimate the size and characteristics of the uninsured in the mid-1980s, the point-in-time definition of the uninsured is used. However, while the number of people who are uninsured will change depending on whether a point-in-time or a longer period of time is used, the general characteristics of the uninsured population are not very different for the two definitions. Thus, while there are pragmatic reasons for choosing the point-in-time definition of the uninsured, it does not create a situation in which the characteristics of the uninsured will be greatly biased in one way or another.

Defining the underinsured population is somewhat more complicated than defining the uninsured. Calling something inadequate implies that there is a standard against which it can be judged. In the case of health insurance, the standard seems to be insurance for unlimited hospitalization/surgical benefits and major medical coverage, with a modest deductible, 20 percent coinsurance payments, a stop loss on out-of-pocket expenditures (i.e., medical expenses not covered by the insurance policy), and high maximum lifetime benefits.

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[1] The upper bound of the estimates for the uninsured is used in this Appendix; i.e., 15.7 percent or 37,180,000 persons, rather than the lower bound of 13.3 percent or 31,010,000 persons summarized in table 1-1.

[2] The Survey of Income and Program Participation (SIPP) was used in 1986 to estimate the uninsured over a period of time, and it will probably receive more attention in the future. The SIPP has had enough attrition from the sample to create problems with developing appropriate weights for the respondents' answers. The Congressional Budget Office (CBO) developed an alternative weighting scheme in the fall of 1987 that appears to give more satisfactory estimates of sub-groups in the population compared to the original weighting scheme. This development should lead to greater use of SIPP. Research on differences and similarities between the CPS and SIPP in terms of health insurance coverage is being conducted by the Census Bureau and by others.

Another standard is an insurance policy with an actuarial value of at least $2,000. By this standard, any policy that is actuarially worth less would be termed inadequate. However, at least two other dimensions other than actuarial value might be included in measuring the adequacy of an insurance policy: 1) the proportion of a person's expected medical expenses that would be covered by the insurance policy, and 2) the proportion of a person's financial resources that is spent on out-of-pocket expenses. For example, suppose two people have identical insurance policies. If one person has large expected medical expenses and the other person has small expected medical expenses, their expected out-of-pocket costs may be different, and the adequacy of their insurance policies may not be the same. But the person who has fewer or none of his or her expected medical expenses covered may have a very high income and could easily afford to pay out-of-pocket expenses. Thus, a person's financial resources must also be taken into account in measuring the adequacy of an insurance policy. (Measuring the adequacy of an insurance policy in terms of out-of-pocket expenses relative to a person's income or total financial resources does not take into account the notion that people should be insured against very expensive illnesses. Insurance against catastrophic medical expenditures generally means that the policy has a limit on out-of-pocket expenses and does not have limits on total expenditures.)

The only source of data that has been used for estimating the underinsured population has been the NMCES. Other surveys that have gathered information on health insurance have not been designed to collect details about the benefits covered by the individuals' health insurance policies. This detailed information has to be verified with employers and insurance companies, which was done with NMCES. The NMCES data has been used to show that the number of people who might be identified as underinsured varies considerably with the way in which adequacy of an insurance policy is measured. However, the characteristics of the underinsured generally did not vary much with the definition used. Nonetheless, three definitions of the underinsured are used in this analysis (87):

1. a five percent expectation that out-of-pocket expenses for medical care will consume more than 10 percent of family income,
2. a 1 percent expectation that out-of-pocket expenses for medical care will consume more than 10 percent of family income, and
3. the insurance policy does not have a limit (stop loss) on out-of-pocket expenditures.

The estimates of how many people under age 65 are underinsured increase from 5.1 percent (11 million) under definition 1, to 8.3 percent (18 million) under definition 2, and to 18.3 percent (38 million) under definition 3.[3]

## Characteristics of the Uninsured Population

The 37.2 million uninsured are disproportionately located in the five southern and western regions of the United States (table A-1). With few exceptions, the States in these regions have stringent eligibility criteria for Medicaid (particularly low income eligibility ceilings) and a shorter history of large union representation among workers, so health insurance as part of wage compensation is less prevalent than it is in the Northeast and Midwest.

Among the uninsured population under 65 years of age, children (persons less than 18 years of age) represent the largest group and account for a third of all the uninsured (table A-2). These 12.3 million children are a fifth of all children in the United States. Twenty-

**Table A-2.—Age Distribution of the Uninsured Population Under the Age of 65, 1986**

| Age | Number of uninsured[a] | | Percent of each age group that is uninsured |
|---|---|---|---|
| 0-17 years | 12,325,000 | (33%) | 19.6 |
| 18-24 years | 7,912,000 | (21%) | 29.2 |
| 25-34 years | 6,860,000 | (19%) | 16.3 |
| 35-44 years | 3,887,000 | (11%) | 12.0 |
| 45-54 years | 2,856,000 | (08%) | 12.6 |
| 55-64 years | 3,058,000 | (08%) | 13.9 |
| Total | 36,898,000 | (100%) | |

[a] Does not include 282,000 persons 65 years or older who are included in tables A-1 and A-3.

SOURCE: U.S. Department of Commerce, Bureau of the Census, "Current Population Survey," unpublished data, March 1986.

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[3] Definition 1 results in fewer underinsured than in definition 2, because definition 1 defines a "costly illness" to include a somewhat lower but more likely level of expense than definition 2 and considers the expectation of out-of-pocket expenditures for medical bills above the 95th (a 5 percent expectation) rather than the 99th (a 1 percent expectation) percentile by risk group. For 4 out of 5 people out of 100 who exceeded this threshold in definition 1, these bills would be much lower than the medical bills of the 1 person in 100 considered in definition 2. When their insurance is measured against these lower expenditures, fewer people in definition 1 than in definition 2 would exceed the thresholds defining the underinsured.

one percent of the uninsured are young adults 18-24 years of age, and these 7.9 million people represent almost 30 percent of all 18-24 year olds. The remaining age cohorts include smaller numbers of people without health insurance and have smaller proportions of people who lack health insurance.

In terms of family income relative to the poverty level (which was about $11,000 for a family of four in 1985), a third of the uninsured have family incomes below the poverty level (table A-3). (Recall that the uninsured are persons with no private or public health insurance, so these 12.3 million people do not meet the eligibility criteria for Medicaid in the States in which they live.) Seventeen percent of the uninsured have family incomes between 1 and 1.49 times the poverty level, and another 13 percent have family incomes between 1.5 and 1.99 times the poverty level. Thirty-eight percent of the uninsured have incomes above two times the poverty level. In terms of the proportions of each income group without health insurance, the risk of being uninsured falls dramatically as family income rises. Among people with incomes below the poverty level, 35 percent are uninsured, while only 7 percent are uninsured among people with incomes three or more times the poverty level. Thus, income is a good simple indicator of the likelihood that a person has health insurance.

Nearly three out of five uninsured adults 18-64 years of age are employed, and 11 percent are unemployed (table A-4). The rest are in categories considered to be out of the labor force. Men constitute almost three out of five employed uninsured adults and almost two-thirds of unemployed uninsured adults. Women constitute two-thirds of the uninsured adults who are out of the labor force. These numbers reflect to some degree the proportions of men in each of the three categories. Men account for 55 percent of all employed adults and 58 percent of all unemployed adults, but only 27 percent of all adults who are out of the labor force. Fifty-six percent of workers without employment-based group health insurance are 18-34 years of age, and employed uninsured adults are more likely to be employed in the service and retail trade sectors of the U.S. economy (279).

### Table A-4.—Labor Force Status of Uninsured Adults Ages 18-64, 1986

| Labor force status | Number of uninsured | | Percent of each labor force status who are uninsured |
|---|---|---|---|
| Employed (full- & part-time) | 14,533,000 | (59%) | 14.2 |
| Unemployed | 2,591,000 | (11%) | 32.4 |
| At school | 1,520,000 | (06%) | 29.1 |
| Unable to work, early retirement | 2,298,000 | (09%) | 22.6 |
| Keeping house | 3,630,000 | (15%) | 18.4 |
| Total | 24,572,000 | (100%) | |

SOURCE: U.S. Department of Commerce, Bureau of the Census, "Current Population Survey," unpublished data, March 1986.

Table A-5 summarizes the relationship between marital status and insurance coverage for adult men. In 1986, 12.6 million men ages 18-64 lacked health insurance. They account for 51.5 percent of all uninsured adults. Nearly half of these uninsured men had never been married. Thirty-five percent of the uninsured men were married and living with their wives, and 9 percent were divorced. Married men living with their wives had the lowest risk of being uninsured. Only 10 percent of these men were uninsured, compared to proportions two to three times higher for the other categories.

The fact that a group has a high risk of being uninsured is not alarming unless there are a lot of people in that group. Thus, the fact that between 23 and 27 percent of divorced, separated, or widowed men are uninsured is not as alarming as the fact that 30 percent of never married men are uninsured, because there are relatively few divorced, separated, or widowed

### Table A-3.—The Uninsured by Family Income Relative to the Poverty Level (all ages), 1986

| Poverty level | Number of uninsured | | Percent of each income group that is uninsured |
|---|---|---|---|
| Below poverty | 12,304,000 | (33%) | 35.0 |
| 1.0-1.49 × poverty | 6,317,000 | (17%) | 27.1 |
| 1.5-1.99 × poverty | 4,712,000 | (13%) | 20.0 |
| 2.0-2.99 × poverty | 6,048,000 | (17%) | 12.9 |
| 3.0 × poverty or greater | 7,799,000 | (21%) | 7.2 |
| Total | 37,180,000 | (101%)[a] | |

[a] Exceeds 100% because of rounding.

SOURCE: U.S. Department of Commerce, Bureau of the Census, "Current Population Survey," unpublished data, March 1986.

### Table A-5.—Marital Status of Uninsured Men, Ages 18-64, 1986

| Marital status | Number of uninsured | | Percent of each marital status who are uninsured |
|---|---|---|---|
| Married | 4,437,000 | (35%) | 10.3 |
| Married, spouse absent | 268,000 | (02%) | 37.3 |
| Divorced | 1,140,000 | (09%) | 22.8 |
| Widowed | 149,000 | (01%) | 23.8 |
| Separated | 444,000 | (04%) | 27.2 |
| Never married | 6,209,000 | (49%) | 30.5 |
| Total | 12,647,000 | (100%) | |

SOURCE: U.S. Department of Commerce, Bureau of the Census, "Current Population Survey," unpublished data, March 1986.

men. These numbers are noteworthy, because men with AIDS are more likely to be never married.

The number of uninsured adult women in 1986 was a little less than the number of uninsured adult men (table A-6). However, the distribution of uninsured women by marital status is different than that observed for men. Whereas 49 percent of uninsured men had never married and 35 percent were married and living with their wives, only a third of the uninsured women had never been married, and 42 percent were married and living with their husbands. About a quarter of never married women were uninsured, compared to 30 percent of their male counterparts. Being divorced, separated, or widowed were more common among uninsured women than among uninsured men. However, the risks of being uninsured for divorced, separated, or widowed women are not very different from the risks of being uninsured for their male counterparts. The proportion of married women who are uninsured is also essentially the same as the proportion for married men.

Thus, men and women who have never been married have the highest risks of being uninsured, and men and women who have been previously married (i.e., divorced, separated, or widowed) have lower but still high risks of being uninsured.

In sum, the 37.2 million uninsured people in the United States are a heterogeneous group. However, in terms of what an AIDS epidemic might mean for the uninsured population, it is noteworthy that a third of the uninsured are adult men (12.6 million of 37.2 million), of whom about half (6.2 million) have never been married.

## Characteristics of the Underinsured Population

As stated earlier, under a strict definition of inadequate health insurance, around 11 million people would have been underinsured in 1986; under a middle definition, 18 million; and under a lenient definition, 38 million. In general, people with nongroup insurance policies are far more likely to be underinsured by any definition of inadequate insurance than people with group policies (87). Furthermore, because most people obtain group insurance policies as part of employment compensation, full-time employees and their dependents are least likely to be underinsured. However, a person has to have some private health insurance to be underinsured, so the proportions of people with different characteristics who are underinsured to some extent provide a mirror image of where private health insurance is more common. For example, under the most lenient definition of inadequate health insurance (i.e., a person does not have a limit on out-of-pocket expenditures), the Northeast region of the country has the highest proportion of underinsured, but the Northeast also has the highest proportion of people with private health insurance.

**Table A-6.—Marital Status of Uninsured Women Ages 18-64, 1986**

| Marital status | Number of uninsured | Percent of each marital status who are uninsured |
|---|---|---|
| Married | 5,066,000 (42%) | 11.1 |
| Married, spouse absent | 192,000 (02%) | 37.7 |
| Divorced | 1,503,000 (13%) | 20.3 |
| Widowed | 736,000 (06%) | 23.4 |
| Separated | 599,000 (05%) | 24.0 |
| Never married | 3,827,000 (32%) | 24.3 |
| Total | 11,923,000 (100%) | |

SOURCE: U.S. Department of Commerce, Bureau of the Census, "Current Population Survey," unpublished data, March 1986.

Table A-7 contains the proportions of people with different characteristics who can be described as underinsured by the three definitions of inadequate insurance. What emerges from this table is that the patterns of being underinsured do not differ between the two definitions that link out-of-pocket expenses with income. For example, poor and near-poor people have the highest proportion of underinsured, and the proportions decline as income rises. In contrast, the most lenient definition of inadequate insurance sometimes yields a different pattern of proportions of underinsured. By this definition, the poor and near-poor have the lowest proportion of underinsured, and the proportion rises as income rises through the low and middle income groups, then falls slightly for the high income group.

In spite of the different effects resulting from different definitions of the underinsured, in general the risk of being underinsured rises as a person's expected out-of-pocket expenditures rise, as people grow older, or as a person's income falls.

## The Links Between AIDS Patients and the Uninsured and Underinsured Populations

By the end of 1987, nearly 50,000 cases of AIDS had been reported to the Centers for Disease Control (CDC), and nearly 28,000 of these people were reported to have died (56). Clearly, the number of living AIDS patients is small compared to the numbers of uninsured or underinsured persons. However, the number of Americans believed to be infected with Human Immunodeficiency Virus (HIV) is estimated to be

### Table A-7.—Underinsured Persons in the U.S. Population Under Age 65: Percentage With Inadequate Coverage According to Alternative Definitions[a]

| Characteristic | 1977 population | Only private and underinsured | | |
|---|---|---|---|---|
| | | Definition 1 | Definition 2 | Definition 3 |
| Total[b] | 189,837,000 | 5.1% | 8.3% | 18.3% |
| *Employment status of household head* | | | | |
| Full-time employee | 136,686,000 | 4.0 | 6.9 | 18.0 |
| Part-time employee | 8,653,000 | 7.3 | 9.2 | 15.0 |
| Self-employed | 17,359,000 | 7.4 | 12.0 | 25.0 |
| Did not work in 1977 | 17,877,000 | 8.2 | 11.0 | 12.8 |
| *Ages in years* | | | | |
| Less than 19 | 69,014,000 | 3.4 | 5.9 | 17.6 |
| 19-24 | 22,109,000 | 6.4 | 9.6 | 13.5 |
| 25-34 | 32,155,000 | 4.2 | 7.4 | 17.0 |
| 35-54 | 46,354,000 | 4.0 | 7.8 | 20.0 |
| 55-64 | 20,206,000 | 13.7 | 17.9 | 24.6 |
| *Family income* | | | | |
| Poor and near poor | 25,413,000 | 15.1 | 17.7 | 10.1 |
| Low | 27,005,000 | 7.7 | 12.3 | 17.3 |
| Middle | 75,238,000 | 3.5 | 7.1 | 20.7 |
| High | 62,182,000 | 1.9 | 4.3 | 19.3 |
| *Perceived health status* | | | | |
| Excellent | 89,027,000 | 3.9 | 6.9 | 19.4 |
| Good | 71,249,000 | 5.6 | 8.8 | 17.8 |
| Fair | 16,881,000 | 8.0 | 12.3 | 16.3 |
| Poor | 4,572,000 | 8.1 | 11.8 | 13.1 |
| *Place of residence* | | | | |
| SMSA | 131,346,000 | 4.4 | 7.4 | 18.0 |
| Not SMSA | 58,492,000 | 6.7 | 10.4 | 19.1 |
| *U.S. census region* | | | | |
| Northeast | 39,915,000 | 5.3 | 9.1 | 23.7 |
| North central | 55,947,000 | 5.0 | 7.3 | 17.4 |
| South | 60,474,000 | 5.5 | 9.2 | 18.6 |
| West | 33,502,000 | 4.5 | 7.5 | 12.9 |

[a] Definitions of underinsured (adjusted for changes in group major medical insurance):
(1) 5 percent expectation of 10 percent of family income in out-of-pocket expenses;
(2) 1 percent expectation of 10 percent of family income in out-of-pocket expenses;
(3) No limit on hospital out-of-pocket expense.

[b] Includes persons for whom employment status of household head and perceived health status are unknown, as well as all other ethnic/racial groups not shown separately.

SOURCE P. Farley, "Who Are the Underinsured?" *Mil. Mem. Fnd Q./Hlth and Soc.* 63(3):476-503, Summer 1985.
U.S. Department of Health and Human Services, Public Health Service, National Center for Health Services Research, and Health Care Technology Assessment, *Health Insurance/Employer Survey: United States 1977*, unpublished data from the National Medical Care Expenditure Survey (NMCES), Hyattsville, MD, 1977.

276,000 to 1.75 million (68). Thus, the potential exists for a large number of people to have AIDS within the next 10 years. The medical care expenses that an AIDS patient can expect to incur before dying place an AIDS patient at risk for being underinsured by even the strictest definition of inadequate insurance. Estimates of such expenses are wide-ranging, but seem to center between $40,000 and $100,000 (121,230,264, 265,271). Moreover, because AIDS frequently causes its victims to be too weak to work, the disease increases the risk that people will lose their link to being insured.

Thus, several factors provide the basis for worrying about the link between AIDS and the uninsured and underinsured populations. First, AIDS may cause people to lose their health insurance, and the costs of medical care for people with AIDS may cause even the insured to be underinsured. Second, there may be large numbers of people who are already infected, which means that there is a potentially large group of people who are very likely to incur large medical expenses and be at risk for being underinsured or uninsured sometime within the next decade.

Among the cases of AIDS reported to CDC, 65 percent of adults have been homosexual or bisexual men without a history of intravenous (IV) drug abuse, 8 percent have been homosexual or bisexual IV drug abusers, 17 percent have been heterosexual male and female IV drug abusers, 3 percent had hemophilia or had received blood transfusions, 4 percent were attributable to heterosexual transmission, and the presumed means of acquiring HIV infection in the remaining 3 percent of adult AIDS cases was unknown. Among the cases of AIDS in children, 77 percent were acquired perinatally (over 70 percent of which were related to IV drug abuse in the child's mother or her sexual partner), 13 percent were associated with transfusions, 5 percent occurred in children with hemophilia, and 5 percent were undetermined (56).

We can probably assume that most of the AIDS patients over the next decade will resemble the current population with AIDS. To the extent that IV drug abusers are unlikely to hold steady jobs with health insurance, the 25 percent of future AIDS victims who are IV drug abusers are least likely to have health insurance. If they have health insurance, it is more likely to be Medicaid, because they may qualify under the Aid to Families with Dependent Children program or the Supplemental Security Income program. The 4 percent of future AIDS cases who are heterosexuals with no history of IV drug abuse are likely to be spouses or lovers of bisexual men or IV drug abusers. If these heterosexuals have incomes below half the poverty level and meet the categorical criteria for Medicaid eligibility (principally, with custody of children or who are disabled), they are likely to be covered by Medicaid. Otherwise, it is difficult to predict whether they have health insurance or not. Hemophiliacs and other recipients of contaminated blood are likely to have health insurance or be covered by Medicaid or Medicare, because the condition that caused them to receive transfusions probably made most of them eligible for coverage if they did not have it before. Furthermore, because of methods to inactivate HIV in blood clotting factors and screening for HIV among blood donors, it is unlikely that this group of AIDS cases will grow rapidly in the future. Most of the children with AIDS acquired it perinatally from their mothers. This population is of growing concern, because it has the potential to expand greatly if heterosexual transmission of HIV becomes widespread. Currently, however, the number of children with AIDS is small, and most are wards of the State and are usually covered by Medicaid.

The largest subgroup among AIDS cases, homosexual or bisexual men with no history of IV drug abuse, is the hardest group to analyze in terms of health insurance coverage. It is difficult to determine whether homosexual or bisexual men are more likely to be employed in sectors of the economy that are less likely to provide health insurance as part of the wage compensation package. If such men are disproportionately employed in service sector or retail trade jobs, then they are more at risk for being uninsured.

Assuming that the vast majority of homosexual men never marry, the fact that half of the uninsured men have never been married, together with the fact that 30 percent of never married men lack health insurance, means that homosexual men are at risk for not having health insurance. (A large proportion of men who abuse IV drugs are also likely to never marry and are at risk for not having health insurance.) Thus, the connections between age, insurance coverage, and whether or not a man has ever been married must be looked at closely. Table A-8 presents further details about the 72 million men in the United States in terms of the proportions of men of different ages who are uninsured, never married, or both never married and uninsured.

Fifty-eight percent of never married, uninsured men are 18-24 years of age. Another 31 percent are 25-34 years of age. Eighty-one percent of men 18-24 years of age have never married, and 32 percent of men 25-34 years of age have never married. Thus, while 89 percent of all uninsured, never married men are between the ages of 18-34, this age cohort also has high proportions of never married men. Consequently, marital status alone (i.e., never married) cannot be used as a proxy for homosexuality or bisexuality.

The Kinsey Institute has estimated that approximately 10 percent of the U.S. population is homosexual. The CDC estimates that there are 2.5 million homosexual men and another 2.5-7.5 million bisexual men and men with very infrequent homosexual contacts. Considering both these estimates, perhaps between 5 and 10 percent of men in the United States are homosexual or bisexual. These percentages approximate the percent of never married men age 35 and over in table A-8, which range from 6-10 percent. Some insurance companies have allegedly used similar characteristics in some parts of the United States—for example unmarried men over the age of 35—as a proxy for homosexuality in attempting to determine an applicant's sexual orientation. However, the similarity between the percentages of never married men age 35 and over in table A-8 and estimates of the total homosexual and bisexual male population in the United States is more likely due to happenstance. For example, there is probably not a one-to-one correlation between marital state and sexual orientation, particularly for bisexual men. Nevertheless, if we extrapolate from these data, there might be between 1 million and 1.8 million uninsured homosexual men between 18-64 years of age. This estimate is arrived at in the following manner. If we disregard the 33 percent of never married men under the age of 25, approximately 25 percent of never married men ages 25-64 are uninsured (table A-8). If we assume that 6 to 10 percent

**Table A-8.—Men 18-64 Years of Age: Percent Uninsured, Percent Never Married, Percent of Never Married Men Who Are Also Uninsured, and Distribution of All Never Married Uninsured Men by Age Cohort, 1986**

| | | Uninsured in age cohort | Never married men in age cohort | Never married, uninsured men in age cohort | |
|---|---|---|---|---|---|
| Age cohort | Number of men | all men in age cohort | all men in age cohort | all never married men in age cohort | Percent of all never married uninsured men |
| 18-24 | 13,657,000 | 32% | 81% | 33% | 58% |
| 25-34 | 20,956,000 | 19 | 32 | 29 | 31 |
| 35-44 | 15,955,000 | 12 | 10 | 22 | 6 |
| 45-54 | 10,970,000 | 12 | 6 | 26 | 3 |
| 55-64 | 10,350,000 | 12 | 6 | 23 | 2 |
| Total | 71,888,000 | 17.6% | 28.3% | 30.5% | 100% |

SOURCE: U.S. Department of Commerce, Bureau of the Census, "Current Population Survey," unpublished data, March 1986.

of men in all age groups are homosexual and that 25 percent of all homosexual men are uninsured, table A-9 provides the estimates of uninsured homosexual men for each of the age cohorts.

## Methods Under Consideration for Reducing the Number of the Uninsured

The three major methods currently under consideration for reducing the number of uninsured are:

1. mandatory employer-provided health insurance for all employees and their dependents of firms employing more than a specified minimum number of employees,
2. expanded Medicaid eligibility to include all people with incomes below some fraction of the poverty level, and
3. allowing people who are categorically ineligible for Medicaid but who have incomes below the poverty level (or some other multiple of the poverty level) to buy into Medicaid on a sliding scale fee basis.

(The Medicaid options are usually discussed with a managed care component.) Many people who can no longer work (including those with AIDS) now have the option under the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1986 to remain in the employer-group for health insurance for up to 18 months, as long as they pay the full insurance premium.[4] For many people with AIDS, 18 months will cover the time between no longer being able to work and death. However, treatment with the drug AZT and other therapies may prolong life beyond these 18 months, and the cost of health insurance may be more than many people with AIDS can afford to pay after they cease working.

Mandating employers to provide health insurance to employees and their dependents would, by some estimates, cover three-quarters of all the uninsured (i.e., about 28 million people). It is the only option currently under consideration that would cover such a large proportion of the uninsured population. For employed people who are at risk for AIDS, this approach would be particularly important, because it provides a mechanism for them to obtain health insurance through group policies, which have lower premium rates than non-group policies.

The employer-provided health insurance proposal that has received the most attention is Senate Bill 1265. This bill would require benefits for prenatal care and well-baby care, and would place the limit on out-of-pocket expenses at $3,000 or 10 percent of annual income. The out-of-pocket limitation is what would most assist employed people who develop AIDS (as well as people with other illnesses and chronic conditions). A catastrophic type of health insurance policy that would limit out-of-pocket expenses to a proportion of a person's annual income would provide similar assistance.

The second major method under consideration for reducing the number of uninsured is to expand Medicaid eligibility to all people below some fraction of the poverty level. This option in particular would help the very poor in States that currently have low income eligibility ceilings. It would also help IV drug abusers and homosexual men with AIDS who do not meet current categorical eligibility criteria for Medicaid, (e.g., custody of children) but who are below the poverty level.

The third major method under consideration for reducing the number of uninsured is to allow people who

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[4] Under COBRA, non-government and non-religious employers with more than 20 employees must give ex-employees the option to remain in the group for health insurance for up to 18 months, as long as the employees pay the employer's and the employee's shares of the premium, plus no more than another 2 percent of the total premium.

**Table A-9.—Estimates of the Number of Uninsured Homosexual Men in Each Age Cohort**

| Age cohort | Total number of men | Estimate of uninsured homosexual men, assuming 6% are homosexual | Estimate of uninsured homosexual men, assuming 10% are homosexual |
|---|---|---|---|
| 18-24 | 13,657,000 | 205,000 | 342,000 |
| 25-34 | 20,956,000 | 314,000 | 524,000 |
| 35-44 | 15,955,000 | 239,000 | 399,000 |
| 45-54 | 10,970,000 | 165,000 | 274,000 |
| 55-64 | 10,350,000 | 155,000 | 259,000 |
| Total | 71,888,000 | 1,078,000 | 1,798,000 |

SOURCE: K. Swartz, "What is the Overlap Between the Uninsured, Underinsured, and People With AIDS?" contract paper in the Urban Institute prepared for the Office of Technology Assessment, U.S. Congress, Washington, D.C., 1988.

are categorically ineligible for Medicaid but who have incomes below some multiple of the poverty level (e.g., 75 percent or 150 percent of the poverty level) to buy into Medicaid on a sliding-scale fee basis. The extent to which this option might reduce the number of uninsured depends on the proportion of the Medicaid premium that would be subsidized. If only a small fraction of the premium is subsidized, it is unlikely that many of the uninsured poor will buy into Medicaid.

Other methods for reducing the size of the uninsured population include pooling risks for small firms, so that premiums per employee for participating small firms are lower. The idea of these Multiple Employer Trusts (METs) is based on the notion that premiums can be lowered for small employers who band together and act as a larger employer. METs have not lived up to expectations along this line, but it is not clear why this is the case. Another method of creating larger risk pools for small firms is to create statewide pools, such as those created by the Federal unemployment insurance tax. Such proposals will lower premiums for employees in small firms but are unlikely to affect many people.

Similarly, risk pools for uninsurable people have been introduced in 15 States for people at high risk for expensive health care services (see app. B). This approach will not greatly reduce the number of uninsured nor assist people with AIDS who do not have large financial resources.

### Appendix B

# Overview of State High Risk Insurance Pools and Catastrophic Health Insurance Plans

## Health Insurance Pools

Roughly 37 million Americans under the age of 65 do not have adequate health insurance. This problem affects different groups of people for varying reasons. Many people find themselves without health insurance because their employers do not offer coverage, their health insurance plans drop them when they become unemployed, they lose dependent coverage through a spouse, or they fall between the cracks of government plans such as Medicaid and Medicare due to eligibility limitations. Some are offered only partial coverage and are not able to obtain supplemental policies to make their health coverage complete, while still others are plagued with pre-existing, long-term illnesses and are, therefore, categorized as "high-risk" individuals and considered virtually uninsurable by commercial insurance plans.

Currently in Federal and State legislatures there is action to establish health insurance pools for underinsured and uninsurable persons. These programs would provide an opportunity for the hard to insure population to purchase health insurance regardless of circumstance or physical condition, although at a rate considerably higher than those of commercial plans. While it is important to create these opportunities for assistance in purchasing health coverage, the pools are not the solution to the overall problem of insurance coverage for the uninsured and underinsured. Due to the high cost of participation in these health insurance pools, they will not benefit those who cannot afford to purchase health insurance.

Although the plans vary from State to State, the basic pattern is that persons who have been turned down by commercial insurers are eligible for participation. Those receiving government assistance are usually disqualified from participation; ten plans will not accept Medicaid recipients and six plans will not accept Medicare recipients. Seven of the fifteen States, however, have a special supplement plan for beneficiaries of Medicare. A choice of deductibles is usually offered, ranging from $150 to $2,000 with correspondingly differing premiums, and a 20-percent coinsurance charge required for all covered expenses. For example, in Connecticut a 35-year-old woman pays quarterly premium rates of $310.44 for a policy with a 20-percent coinsurance and a $1,000 deductible.

Typically, all health insurance companies within the State organize and elect one company to administer the plan under regulations established by State law. Even with high premium rates, the premiums are generally insufficient to cover the costs of the claims. Most States cover losses by assessing the health insurance companies in proportion to each company's share of the State health insurance market, the companies, then, deduct these payments from premium and income taxes. Two exceptions are Illinois and Maine who use general revenue funds and tax hospital patient services revenue, respectively, to cover pool losses.

A major point of contention regarding this legislation is that increasing numbers of employers are opting to insure their employees through employee benefit programs; that is, they are using self-insured plans in lieu of operating through a commercial insurance firm. A group health plan offered by an insurance company is subject to State regulations, while self-insured plans, those which are financed and run by an employer without using an insurance company, have been determined by the U.S. Supreme Court in 1981 to be exempt from State insurance regulations and are, instead, governed by the Employee Retirement Income Security Act (ERISA). ERISA establishes Federal guidelines for employee benefit plans and preempts all State laws that relate to such plans. Self-insured plans, then, are subject to almost no regulations, including State requirements to contribute to the health insurance pool when losses are incurred. Insurance companies claim that this gives employers an incentive to fund their own plans, thereby avoiding State insurance regulatory requirements as well as escaping mandatory participation in health insurance pools. The insurance industry is willing to implement the health insurance pool plan and, in fact, supports the idea, but only if self-insured plans are subject to the same regulations regarding contributions to the pool association. The insurance industry wants Congress to amend ERISA so that self-insured plans are included. Self-insured plans want to maintain the law as it stands now, arguing that the problem of paying for health care for uninsured people is not an employer's concern but rather one for which society should be responsible.

Legislation has been introduced at the Federal level that would provide incentives for employers to participate in health insurance pools by mandating certain penalty taxes to be applicable to both self-insured plans and commercial plans if either fails to comply with health pool regulations. Senators Dave Durenburger and Donald Reigle are among the leading legislators on this issue, persistently proposing legislation to promote the establishment of health insurance pools. Table B-1 provides a brief synopsis of the major legislative attempts of the 100th Congress regarding health insurance pools. As it is early in the legislative session, more proposals are promised to surface in the following months. Fifteen States have already established health insurance pools. The first programs were established in Connecticut in 1975 and in Minnesota in 1976, followed by Wisconsin and North Dakota in 1981, then Indiana in 1982 and Florida in 1983; plans in Iowa, Montana, and Tennessee began operation in 1987 while the plans in Illinois, Washington, New Mexico, Maine, and Oregon plan to be functioning by 1988. Table B-2 provides a comparison of these plans. Descriptions of each of the State health insurance plans are provided below. Unless otherwise indicated, each plan's benefits include hospital services, professional diagnostic and treatment services (other than dental), skilled nursing facility services, home health services, oral surgical services, prescription drugs, and rental of durable medical equipment.

## Connecticut

The Connecticut Comprehensive Health Care Plan was created in 1975 to help meet medical costs of nonoccupational injuries and diseases.

### Eligibility

Any State resident, including Medicare recipients under 65 but excluding those eligible for Medicare solely because of age, is eligible for pool membership. There is no waiver of the 12-month waiting period required for an existing medical condition or one treated within 6 months prior to coverage unless the applicant is converting directly from a Connecticut-issued group contract. The group contract must remain in effect and the applicant must have been insured by the group plan for at least a year. Eligibility for the plan differs somewhat from other State plans in that there

**Table B-1.—Congressional Bills on High-Risk Insurance Pools (1987)**

S. 1634: Sen. Durenburger; The Access to Insurance for the Medically Uninsurable Act of 1987

Encourages States to set up pooling mechanisms through a $10 million grant program. States will receive funds based on their proportionate share of the national population to be used toward establishing health insurance risk pools. The States themselves would be responsible for financing, design, and subsidization of the pools.

S. 177: Sen. Reigle; Health Care for the Uninsured Act of 1987

Permits States to establish health care pools to provide health care services to all uninsured individuals and share among all hospitals in the State the costs of uncompensated care. Requires the implementation of the health care pool at the Federal level where a State does not establish such a program or receive a waiver from the Secretary of Health and Human Services. Uninsured individuals wishing to secure health coverage through the pool will pay a premium for such coverage based on the individual's family income.

S. 1139: Sen. Chafee; MedAmerica Act of 1987

Amends the Social Security Act to give States the option of extending coverage to individuals whose family income does not exceed an income level established by the State at or below 200 percent of the Federal poverty level, who are unable to obtain health insurance coverage from another source by reason of a preexisting medical condition, have exhausted some or all benefits under their health insurance policy, and whose employer employs no more than 25 individuals and is unable to provide adequate health insurance coverage for such individuals at a reasonable cost. Also offers provision to those with catastrophic health expenses who have exhausted private insurance coverage or who have a pre-existing condition and are therefore denied by private insurers, by allowing them to purchase Medicaid coverage at full premium with no income adjustment.

H.R. 406: Rep. Roe; National Catastrophic Illness Protection Act of 1987

Establishes a national catastrophic illness insurance program under which the Federal government, State insurance authorities, and the private insurance industry cooperate to make available adequate health protection to all Americans at reasonable cost. State-wide plans providing extended health insurance will be provided and the Federal government will reinsure insurers and pools of insurers who offer such insurance.

H.R. 1182: Rep. Regula; Health Services Act of 1987

Amends Title XIX of the Social Security Act to establish a public/private program providing health services to the medically uninsured. Provides benefits to residents of a State where there exists a Statewide Pooling Corp. and establishes a Federal Health Trust Fund to pay direct grants to such corporations. Employers who are not members of the corporation will be taxed, the revenues going to the trust fund.

SOURCE: Office of Technology Assessment, 1988.

## Table B-2.—State High-Risk Insurance Pools Summary of Plans

| State | Enactment date | Plan administrator | Maximum lifetime benefits | Deductibles[a] | Premium caps | Stop/loss | Medicare supplement plan | 1986 enrollment | Pool funding |
|---|---|---|---|---|---|---|---|---|---|
| Connecticut | 1975 | The Travelers | $1,000,000 | $400<br>$1,000<br>$1,500 | 125%, 150% | $2,000/Individual<br>$4,000/Family | No | 3,101 | Insurers assessed, no tax credit |
| **Florida** | **1983** | **Mutual of Omaha** | **$500,000** | **$1,000<br>$1,500<br>$2,000** | **200%** | ***Regular***<br>**$2,500/Individual; $5,000/Family<br>$3,000/Individual; $6,000/Family<br>$3,500/Individual; $7,000/Family**<br>***Medicare***<br>**$1,500/Individual; $4,000/Family<br>$2,000/Individual; $4,500/Family<br>$1,500/Individual; $5,000/Family** | **Yes** | **855** | **Insurers assessed with tax credit** |
| Illinois | 1988 | Not awarded | $500,000 | $250/500/1,000/Individual<br>$500/1,000/1,500/Family | 135% | $1,500/Individual; $3,000/Family<br>$500/Medicare recipient | No | — | General revenues |
| **Indiana** | **1982** | **Mutual of Omaha** | **Plan I-no limit<br>Plan II-$50,000** | **$200<br>$500<br>$1,000** | **150%** | **Plan I<br>$1,000/Individual; $2,000/Family<br>Plan II<br>$1,000/Individual; $2,000/Family<br>$1,500/Individual; $3,000/Family<br>$2,000/Individual; $4,000/Family** | **No** | **3,229** | **Insurers assessed with tax credit** |
| Iowa | 1987 | Mutual of Omaha | $250,000 | $500<br>$1,000<br>Others designated by the board | 150% | A. $1,500/Individual; $3,000/Family<br>B. $2,000/Individual; $4,000/Family | Yes | — | Insurers assessed with tax credit |
| **Maine** | **1986** | **Not awarded** | **$500,000** | **Between $500 & $1,000** | **150%** | **No more than<br>$1,500/individual<br>$3,000/family** | **No** | **—** | **Tax on hospital patient services revenue** |
| Minnesota | 1976 | Blue Cross/ Blue Shield | Regular plan $250,000<br>Medicare plan $100,000 | $500<br>$1,000 | 125% | Regular plan-$3,000/Individual<br>Medicare supplement-$1,000/Individual | Yes | 10,439 | Insurers assessed no tax credit |
| **Montana** | **1987** | **Blue Cross/ Blue Shield** | **$250,000** | **Not to exceed $1,000** | **150%, 400%** | **$5,000/Individual** | **No** | **—** | **Insurers assessed with tax credit** |
| Nebraska | 1987 | Blue Cross/ Blue Shield | $500,000 | $250<br>$500<br>$1,000 | 135%, 165% | $5,000 | No | 67 | Insurers assessed with tax credit |
| **New Mexico** | **1988** | **Not awarded** | **None** | **$500<br>$1,000** | **150%** | ***$500 Deductible***<br>**$1,500/Individual; $2,500/Family**<br>***$1,000 Deductible***<br>**$2,000/Individual; $3,000/Family** | **No** | **—** | **Insurers assessed, partial tax credit** |
| North Dakota | 1981 | Blue Cross/ Blue Shield | $250,000 | $150<br>$500<br>$1,000 | 135% | $3,000/Individual | Yes | 1,131 | Insurers assessed with tax credit |
| **Oregon** | **1988** | **Not awarded** | **$1,000,000** | **Not yet determined** | **150%** | **Not yet determined** | **No** | **—** | **Partial insurer assessment** |
| Tennessee | 1987 | Mutual of Omaha | $500,000 | $500<br>$2,000<br>Others designated by the board | 150% | A. $1,500/Individual; $2,500/Family<br>B. $2,500/Individual; $3,500/Family | Yes | — | Insurers assessed with tax credit |
| **Washington** | **1988** | **Not awarded** | **$500,000** | **$500<br>$1,000** | **150%** | ***$500 Deductible***<br>**$1,500/Individual; $3,000/Family**<br>***$1,000 Deductible***<br>**$2,500/Individual $5,000/Family**<br>***Medicare supplement***<br>**$1,000** | **Yes** | **—** | **Insurers assessed with tax credit** |
| Wisconsin | 1981 | Mutual of Omaha | $500,000 | $500 (Medicare Part A)<br>$1,000 | 150% | Plan I<br>$2,000/Individual; $4,000/Family<br>Plan II (Medicare) $500 | Yes | 1,964 | Insurers assessed, no tax credit (subsidy from general revenues) |

[a] All plans also have a 20% coinsurance requirement (excepting Nebraska where the coinsurance payment is 10%).

SOURCE: Office of Technology Assessment, 1988.

is no requirement that one must be rejected by a commercial plan prior to applying for membership in the pool. Because of this, the plan attracts many good risks such as those between jobs, recent school graduates not yet employed, and group conversions.

### Payments and Benefits

There is a 20-percent coinsurance required for all covered expenses and deductibles of $400, $1,000, and $1,500 are offered. The maximum lifetime benefit is $1,000,000. The premium cap is no less than 125 percent initial and no more than 150 percent of the average group premium rate offered for comparable coverage. Stop loss/out-of-pocket expenses are limited to $2,000 for an individual and $4,000 for a family. There is no Medicare Supplement Plan, as Medicare beneficiaries are ineligible to participate.

### Administration

The pool is governed by a board of seven individuals selected by participating pool members. The Travelers Insurance Company administers the plan, and there are special provisions for Blue Cross/Blue Shield (BC/BS). In the past, BC/BS operated an identical plan and was not required to pay assessments on the State operated plan. In 1984, however, BC/BS became mutualized and, although it continues to cover it's existing policyholders of over 25,000 individuals, it now refers uninsurables to the State pool. All health insurance carriers, including health care service plans, health maintenance organizations authorized to issue insurance in the State, and self-insured employer health benefit plans established in the State after 1976 (however, self-insurers can no longer be obligated to join), are required to be members of the pool and are assessed in proportion to their share of the State insurance market. The enrollment dropped from 4,399 in 1983 to 3,101 as of August 1, 1986. In calendar year 1985, the members shared an estimated loss of $1,533,000.

## Florida

The 1983 Florida Comprehensive Health Insurance Plan is designed to provide adequate health insurance coverage to those unable to procure coverage in the private market due to their mental or physical condition.

### Eligibility

To be eligible, an individual must be a Florida resident ineligible for Medicaid who has been rejected by at least two health insurers for similar coverage, or who has received notice of benefit reduction, condition exclusion, or premium increase exceeding the rate for pool coverage. There is no waiver of the 6-month waiting period for any illness diagnosed or treated within 6-months of policy date.

### Payments and Benefits

Deductibles of $1,000, $1,500, and $2,000 are available, accompanied by a 20-percent coinsurance requirement. There is a $500,000 maximum lifetime benefit and a premium cap of 200 percent of the average plan for comparable coverage. Stop loss/out of pocket expenses can vary from $2,500 to $3,500 for an individual and from $5,000 to $7,000 for a family. Benefits include limited mental health services and the option to purchase durable medical equipment, but do not include home health care services or oral surgical services. A Medicare Supplement Plan is included.

### Administration

The plan is administered by Mutual of Omaha as of 1986, and is governed by a seven-member board. The board is composed of three members appointed by the Insurance Commissioner (one from the general public, one from medical providers, and one from health insurance agents) and four members appointed by participating insurers (at least one from a nonprofit insurer and one from a domestic insurer). All health insurance carriers, including health care service plans authorized to issue insurance in Florida but excluding health maintenance organizations, are required to participate in the pool. All pool members are assessed in proportion to their share of the State insurance market and can credit their assessments against State premium and income taxes. The number of citizens taking advantage of the pool is low, 1,036 as of December 1986, yet represents a substantial increase from the 49 enrollees in 1983. During the first year of operation the Florida plan was unique in that it recorded no losses. However, by 1985 the 1-year waiting period was changed to 6 months, the enrollment increased and the plan began assessing members for pool losses as do other plans.

## Illinois

The Comprehensive Health Insurance Plan for Illinois was created to provide satisfactory insurance coverage for those unable to purchase traditional health insurance because they are perceived as high-risk persons. The plan passed into law in early 1987 but has postponed the operational date. If appropriations are granted, the plan will open in August 1988.

### Eligibility

All Illinois residents are eligible for pool membership who do not qualify for Medicaid coverage, have been rejected for health insurance coverage for health reasons by an insurance company, or were offered coverage at a rate exceeding the plan's rate. Additionally, those suffering from a condition listed by the plan automatically satisfy eligibility requirements. A waiting period of 6 months is required for pre-existing conditions manifested or treated within 6 months prior to the effective date of coverage. An additional premium of up to 10 percent of the annual premium (to be effective for the life of the contract) can be chosen. This coverage would exclude charges or expenses incurred during the first 2 months of coverage date for any condition manifested or treated within 2 months preceding coverage effectiveness. A group of 10 or less is eligible for membership if one or more of the group meets the above pool criteria.

### Payments and Benefits

A 20-percent coinsurance payment is required in addition to the deductible charge which can be $250, $500 or $1,000 for an individual and $500, $1,000 or $1,500 for a family. The maximum lifetime benefit is limited to $500,000 and the premium is capped at 135 percent. Stop- loss/out-of-pocket expenses are set at $1,500 for an individual, $3,000 for a family and $500 for Medicare recipients. Benefits include hospice care, physical, speech and occupational therapy, and some outpatient mental health coverage. No Medicare Supplement Plan is offered.

### Administration

The plan administrator has not yet been named. A board of 11 people will oversee the plan including representatives from participating insurers, public members, the Illinois Health Care Cost Containment Council, the Office of the Attorney General and members of the General Assembly (nonvoting). Costs of the plan are to be paid from the premiums. If, however, costs exceed the premiums received, the deficit will be paid out of the general revenues of the State.

## Indiana

The Indiana Comprehensive Health Insurance Association was enacted in 1982 to offer health insurance for those residents who find it difficult to obtain or keep health insurance due to a medical condition.

### Eligibility

Any Indiana resident not eligible for Medicare who has been rejected by two health insurers for similar health coverage or who has received notice of benefit reduction, condition exclusion, or premium increase exceeding the rate of pool coverage is eligible for pool participation. There is a 6-month waiting period for a pre-existing condition treated 6 months prior to the policy date, which can be waived on request (for a 25 percent premium increase) if other health insurance was effective immediately before pool coverage began or if application for pool coverage was within 60 days of becoming eligible. Indiana also includes a provision for any individual suffering from a specified illness (e.g., cancer) listed on the premium rate page which merits automatic eligibility for pool coverage.

### Payments and Benefits

In addition to a 20-percent coinsurance requirement, two deductible plans are offered, one with a $200 deductible, the other with a choice of a $200, $500, or $1,000 deductible. There is no maximum benefit limit, however, under plan II there is a $50,000 benefit cap for mental and nervous disorders. The premium cap is set at 150 percent. Stop loss/out-of-pocket expenses vary by plan: plan I sets $1,000 for an individual and $2,000 for a family, while plan II ranges from $1,000 to $2,000 for an individual and from $2,000 to $4,000 for a family. Benefits include limited mental health services. There is no Medicare Supplement Plan available as Medicare beneficiaries are ineligible to participate.

### Administration

A board of five to nine people oversees the plan, administered by Mutual of Omaha. All health insurance carriers, including health care service plans, health maintenance organizations authorized to issue insurance in the State, and self-insured employer health benefit plans (self-insurers can no longer be obligated to join), are required to participate in the pool association. All pool members are assessed in proportion to their share of the State insurance market and can credit assessments against State premium and income taxes and can increase rates to offset assessment. The Indiana plan has increased it's enrollment to 3,229 in 1986 from the 41 people it served during the first year in operation. Calendar year 1985 showed an estimated loss of $3,339,000 for the pool.

## Iowa

The Iowa Comprehensive Health Insurance Association began service in 1987.

### Eligibility

All Iowa residents ineligible for Medicaid who have been rejected by one insurer for similar health insurance coverage, or who were only offered health coverage at a rate exceeding the pool rate, are eligible to participate in the pool.

### Payments and Benefits

Along with 20-percent coinsurance, deductibles of $500, $1,000 or any other amount authorized by the board are offered. There is a $250,000 lifetime maximum benefit and a 150-percent premium cap. Stop loss/out-of-pocket expenses vary between plans, with limits of $1,500 or $2,000 for an individual and $3,000 or $4,000 for a family under plan I and plan II, respectively. Benefits include limited mental health services. A Medicare Supplement Plan is available and provides coverage of at least 50 percent of the deductible and 80 percent of covered expenses, with Medicare plan premiums to be determined by the board.

### Administration

The plan administrator is Mutual of Omaha. Between five and nine people comprise the board, including one public member selected by the Insurance Commissioner and four to eight selected by the members of the association. All health insurance carriers, including health care service plans and health maintenance organizations authorized to issue insurance in the State, are required to be members of the pool. All pool members are assessed in proportion to their share of the State insurance market and can credit assessments against State premium and income taxes.

## Maine

The Maine High-Risk Insurance Organization will be in effect July 1, 1988 for those persons who are unable to obtain health insurance coverage for medical reasons.

### Eligibility

To be eligible for coverage under the risk pool one must be a resident of the State and either be unable to procure adequate coverage or is being charged higher premium prices by the current carrier than those offered in the pool. Those receiving Medicare and Medicaid benefits are exempt from risk pool coverage. The pool offers major medical expense coverage to every eligible person up until a 300-person maximum enrollment is reached (unless legislative approval is given to expand). A 90-day waiting period is in effect for any condition which was diagnosed or for which treatment or medical advise was sought during the 90-day period preceding the effective date of coverage. The pre-existing-condition waiting period can be waived if similar exclusion stipulations have been met under previous coverage involuntarily terminated if the pool application is made within 31 days following the involuntary termination and no conversion plan is available at equal or less cost than risk pool costs. Additionally, the waiver is granted if $3,500 has been paid for uncovered medical expenses (exclusive of the deductible) during the 90-day waiting period in which case the remainder of the waiting period will be waived. Also, any person enrolling in the plan during the first 6 months of operation will not be subject to the preexisting condition waiting period exclusion.

### Payments and Benefits

Deductibles will be no less than $500 and no more than $1,000. There is a $500,000 maximum lifetime benefit and premium cap of 150 percent maximum. Stop loss/out-of-pocket expenses are not to exceed $1,500 for an individual and $3,000 for a family. No Medicare Supplement Plan is available as Medicare recipients are not eligible for pool coverage. The pool will also subsidize premiums for individuals denied health insurance due to a health condition and who meet income eligibility requirements set by the board. The subsidy plan will be paid from the General Fund and shall not exceed $50,000 in costs during the first 2 years of operation. No subsidy will be given to a person if the premium amount, after deducting the subsidy, is less than the premium of any comparable individual health insurance policy currently available to that person in the State.

### Administration

The governing board will consist of seven members including two members representing consumers of health insurance not otherwise affiliated with the provision of health care financing, one member representing domestic commercial insurers, one representing nonprofit hospital and medical service organizations, one representing hospitals and one member being the Superintendent of Insurance or a designee from that office. The Maine pool will be financed through the Reserve Fund established to cover any expenses and claims above premium income. The reserve will be funded by assessing the revenues of all hospitals in the State. The amount of the assessment is not to exceed .0015 percent of all hospitals' gross patient services revenues and will be adjusted annually by the board. However, under the Maine law enacting the risk pool, the pool will cease enrollments and renewals of participants by June 30, 1991 and if the legislature decide to renew the law, the committee with jurisdiction will consider methods of funding the reserve fund other than by assessing the hospitals.

## Minnesota

The Minnesota Comprehensive Health Association was created in 1976 to make the minimum benefits of hospital and medical-surgical expense coverage available to all State residents.

### Eligibility

An eligible individual must be a State resident who has been rejected by one insurer for similar health insurance coverage, or was offered health coverage with a restrictive rider which decreases benefits, or had a preexisting condition limitation within 6 months prior to enrolling in the pool plan. Individuals who have been treated for certain chronic health conditions within 3 years of pool application are automatically eligible for pool coverage regardless of other requirements.

### Payments and Benefits

Deductibles of $500 and $1,000 are available and a 20-percent coinsurance payment for all covered services is required. A Medicare Supplement Plan is available. The maximum lifetime benefit for the Medical-Surgical Plan is $250,000 and $100,000 under the Medicare Supplement Plan. There is a premium cap of 125 percent, and the stop loss/ out-of-pocket expenses are $3,000 per person for the Medical-Surgical plan and $1,000 per person for the Medicare plan. Benefits include well-baby care and the option to purchase durable medical equipment.

### Administration

Blue Cross/Blue Shield is the plan administrator, and the board consists of seven individuals selected by pool members and two appointees of the Governor. All health insurance carriers, including health care service plans and health maintenance organizations authorized to issue insurance in the State, are required to be members of the pool. Self-insurers were previously required to participate but are now exempt because of ERISA. All pool members are assessed in proportion to their share of the State insurance market. However, members can no longer credit assessments against State premium taxes as that privilege was repealed as of January 1987. This plan served 10,439 people as of May 1, 1986, an increase from 2,918 in 1981. $5,507,000 of estimated pool losses were reported in calendar year 1985.

## Montana

The Montana Comprehensive Health Association, operational in July 1987, was created to provide adequate health insurance coverage to all State residents otherwise considered uninsurable.

### Eligibility

All State residents who have been rejected by two health insurers or who have had restrictive rider or pre-existing condition limitations imposed by two insurers within 6 months prior to pool application are eligible for pool participation. There is no waiver for the 12-month waiting period established for any preexisting condition diagnosed or treated during the past 5 years immediately preceding pool application. An individual who had continuous coverage under a policy during the previous year is exempt from the preexisting condition clause.

### Payments and Benefits

Deductibles are not to exceed $1,000 in addition to the 20-percent coinsurance requirement. The lifetime maximum benefit is $250,000. The premium cap is set at no less than 150 percent and no more than 400 percent, the stop loss/out-of-pocket expense is set at $5,000 for an individual. Benefits include the option to purchase durable medical equipment but do not include skilled nursing facility services. There is no Medicare Supplement Plan, even though the law does not specifically prohibit participation by Medicare beneficiaries.

### Administration

The plan administrator is Blue Cross/Blue Shield. The board is comprised of eight members, one from each of the seven participating members with the highest annual premium volume of disability insurance or health service contracts, and one member appointed by the Insurance Commissioner to represent the public interest and who serves in an advisory capacity. All health insurance carriers, including health care service plans and health maintenance organizations authorized to issue insurance in the State, are required to be members of the pool. All pool members are assessed in proportion to their share of the State insurance market and can credit assessments against the State premium tax.

## Nebraska

The Nebraska Comprehensive Health Insurance Pool, operational in 1987, was established to provide health insurance coverage to all State residents regardless of pre-existing medical conditions.

### Eligibility

All persons who have been State residents for at least 6 months, who are ineligible for Medicare, Medicaid, or other medical assistance and who, within 6 months prior to applying to the pool, were rejected by one health insurer or had coverage with a restrictive rider which limits coverage for more than 12 months, and those individuals with coverage at a rate higher than the pool rate, are eligible for coverage. A waiting period of 6 months is required for any condition which manifested itself during the 6-month period preceding the policy date, but a waiver is provided if similar exclusions have been satisfied under prior health insurance coverage (the board may assess an additional premium of up to 10 percent for this waiver).

### Payments and Benefits

Deductibles of $250, $500, and $1,000 are offered, with a 10-percent coinsurance required for all covered expenses. A $500,000 maximum lifetime benefit is set. There is a premium cap of no less than 135 percent and no more than 165 percent. Stop loss/out-of-pocket expenses are set at $5,000. Benefits include limited mental health services and the option to purchase durable medical equipment, but do not include oral surgical services. There is no Medicare Supplement Plan, as Medicare beneficiaries are ineligible to participate.

### Administration

Blue Cross/Blue Shield is the plan administrator, and the board is comprised of nine members, including at least one representative of a domestic insurance company, one representative of a domestic hospital service corporation plan, one representative of a health maintenance organization, and one representative of the general public. All health carriers, including health care service plans and health maintenance organizations authorized to issue insurance in the State, are required to be members of the pool. All pool members are assessed in proportion to their share of the State insurance market and can credit assessment against the State premium tax. During the plan's first year of operation, it served 67 people.

## New Mexico

The New Mexico Comprehensive Health Insurance Pool, scheduled for operation by January 1988, was created to assist all State residents considered uninsurable or who are denied adequate health insurance.

### Eligibility

Those State residents having received a rejection of health insurance coverage, a rate increase exceeding the pool rates, or a reduction or limitation of coverage (including a restrictive rider), and do not qualify for Medicare or Medicaid benefits are eligible for pool coverage. The plan enforces a 6-month waiting period for those conditions that manifested themselves within 6 months prior to pool coverage or for which medical advice or treatment was sought within 6 months before coverage was effective. Unique to the New Mexico Plan is a conversion provision for those moving to New Mexico from a State where they were covered under the State health insurance pool. If application for pool coverage is completed within 31 days after the termination of the other policy and premiums were paid for the entire coverage period, the effective date of the new coverage will be the termination date of the previous coverage. If waiting period stipulations were satisfied and benefit limitations were not reached under the previous plan then the waiting period under the new plan is waived.

### Payments and Benefits

Deductibles of $500 or $1,000 are offered unless otherwise approved by the board. There is no maximum lifetime benefit and the premium is capped at 150 percent. The stop loss/out-of-pocket costs are $1,500 for an individual and $2,500 for a family under the $500 deductible plan and $2,000 or $3,000 for an individual or family respectively under the $1,000 deductible plan. No Medicare Supplement Plan is included in the New Mexico Pool. Another unique feature of the New Mexico Plan is the provision stating that employers are authorized to "make a payroll deduction from the compensation of an employee for the portion of the pool policy premium the employee is responsible for, and an employer shall contribute the same dollar amount of the cost of that policy on behalf of the employee that the employer contributes for other similar employees for health insurance."

### Administration

The 10-member board composition will include the Superintendent or his designee, one representative from a nonprofit health care plan, one from an HMO, and two representatives from members of the pool, all 4 of which will be appointed by members of the pool. Additionally, the Superintendent will appoint five members including one representative of Statewide health planning and four citizens not professionally affiliated with an insurer, two of which will be individuals qualifying for coverage under the pool. Pool losses are assessed to all members yet no credit will be given on future taxes until one member's assessment reaches $75,000 per year at which point the member will receive a 30-percent tax credit for the amount paid over $75,000.

## North Dakota

In 1981 North Dakota created The Comprehensive Health Association to provide health coverage for those denied health insurance, given only restricted coverage due to health problems, or who were considered to be in a high risk category.

### Eligibility

Any individual who has been a North Dakota resident for at least 6 months and who has written evidence of rejection by one insurer or a restrictive rider or a pre-existing condition limitation from at least one insurer within 6 months prior to the date of enrollment is eligible for pool membership. There is a 6-month waiting period for any condition diagnosed or treated within 90 days prior to the policy date. The waiting period can, however, be waived upon payment of an additional premium or proof of continuous coverage for the 12-month period immediately preceding the contract date.

### Payments and Benefits

Along with the required 20-percent coinsurance, deductibles of $150, $500, and $1,000 are offered. The maximum premium cap is set at 135 percent. The maximum lifetime benefit is $250,000. The stop loss/out-of-pocket expense is limited to $3,000 for all deductibles. Benefits include the option to purchase durable medical equipment. A Medicare Supplement Plan is offered.

### Administration

Blue Cross/Blue Shield of North Dakota administrates the plan. Ten board members, 1 from each of the 10 insurers with the highest annual premium volumes, govern the association. All health insurance carriers are required to participate. This includes all health care service plans authorized to issue insurance in the State, although health maintenance organizations are excluded. All pool members are assessed in proportion to their share of the State insurance market and can credit assessment against State premium and income taxes. This plan served 1,131 people as of May, 1986, an increase from the 78 people served during it's first full year of operation.

## Oregon

The Oregon Medical Insurance Pool was created to offer health insurance coverage to all State residents denied adequate medical insurance while also avoiding undue financial impact on the State and private insurers. The plan is scheduled to go into effect in the Spring of 1988.

### Eligibility

Those applying for pool coverage must be residents of Oregon ineligible for Medicaid and Medicare and have proof from an insurer of an adverse underwriting decision on medical insurance for health reasons, proof of a history of any medical or health condition on the list adopted by the board (the board may adopt a list of medical or health conditions for which a person is eligible for pool coverage without proving that they were denied medical insurance), or must be a spouse or dependent of a person described under this eligibility. A six-month pre-existing condition waiting period is enforced for any condition for which treatment, care, or medical advise was sought within the six-month period preceding the effective date of pool coverage. The pre-existing condition waiting period can be waived if similar exclusions have been satisfied under prior health insurance involuntarily terminated, provided pool application is made within 60 days following the involuntary termination.

### Payments and Benefits

The deductibles and stop loss/out-of-pocket expenses have not yet been determined by the board although a maximum lifetime benefit of $1,000,000 and a premium cap of 150 percent initial maximum have been set. No Medicare Supplement Plan will be offered.

### Administration

The board will be composed of seven members selected by pool members. The commissioner or a designee will serve as the chair of the board. Other members will include at least one representative of a domestic insurance company licensed to transact health insurance; one representative of a domestic not-for-profit health care service contractor; and one member of the general public not associated with the medical profession, a hospital, or an insurer. The members of the Oregon pool will consist of all insurers issuing medical insurance within the State and, to the extent Federal law allows, self-insurance arrangements either covered or not by ERISA, including governmental and church plans. The plan Administrator has not yet been named. Deficits incurred under the risk pool will be paid by the State. Members of the pool may be assessed for an amount not to exceed $150,000 to cover initial operating expenses. However, the plan has a built-in protection against losses to the pool. While benefits and premiums will be adjusted annually, pool losses are to be kept at under 1 percent of the total of all medical insurance premiums, subscriber contract charges, and 110 percent of all benefits paid by member self-insurance arrangements. The board can also place a ceiling on the maximum number of persons enrolled.

## Tennessee

The Tennessee Comprehensive Health Insurance Pool, created in 1986 and effective in July 1987, was established to provide health insurance coverage to State residents denied adequate health insurance for any reason.

### Eligibility

All residents not eligible for Medicaid and who have been rejected for similar coverage by one health insurer are eligible for pool coverage. There is no waiver for the 6-month waiting period for any condition which manifested itself or was treated within 6 months prior to the policy date.

### Payments and Benefits

Deductibles of $500, $2,000, and any other offered by the board will be available, with a 20-percent coinsurance for all covered expenses required. The premium cap is set at 150 percent. The maximum lifetime benefit is $500,000. The stop loss/out-of-pocket expenses range from $1,500 to $2,500 for an individual and from $2,500 to $3,500 for a family, depending on the plan. Benefits include limited mental health services and the option to purchase durable medical equipment. A Medicare Supplement Plan will be offered.

### Administration

Mutual of Omaha admistrates the plan. The board is composed of nine members, with at least one representative of a domestic insurance company; a foreign insurance company; a domestic non-profit health care service plan; a health maintenance organization; a member from a health-related profession; one member from the general public not associated with the medical profession, a hospital, or an insurer; and one member to represent a group considered to be uninsurable. All health insurance carriers, including health care service plans and health maintenance organizations authorized to issue insurance in the State, are required to participate in the pool association. If premiums do not cover costs, all pool members will be assessed in proportion to their share of the State insurance market and can credit assessments against the State premium tax.

## Washington

The Washington State Health Insurance Pool began operating in January 1988 to assist all State residents denied adequate health insurance.

### Eligibility

Any Washington resident is eligible for pool participation who does not qualify for Medicaid coverage and has proof of rejection for health insurance coverage from at least one insurer or who has insurance with a restrictive rider or a pre-existing condition limitation which reduces the coverage from a standard risk within 6 months of the date of application. There is a 6-month waiting period for any condition for which advice or treatment was sought within 6 months before the effective date of coverage. The pre-existing condition clause can be waived if the individual applies for membership within 30 days of being involuntarily terminated from prior coverage under which similar exclusion stipulations were met.

### Payments and Benefits

Deductibles of $500 and $1,000 (or an amount approved by the board) are offered. The maximum lifetime benefit is $500,000 and the premium cap is set at 150 percent. The stop loss/out-of-pocket expenses are $1,500 for an individual and $3,000 for a family for those who choose the $500 deductible plan, $2,500 for an individual and $5,000 for a family for those on the $1,000 deductible plan, and $1,000 for an individual on the Medicare Supplement Plan.

### Administration

The pool is governed by a nine-member board. A representative of health care providers, health insurance agents, and the general public will be appointed by the commissioner. The remainder of the board is selected by the pool members and includes at least one health care service contractor, one representative of a health maintenance organization, and one representative of commercial insurers providing disability insurance. Self-insurers will be included as soon as Federal law permits their participation. Pool members are assessed for any deficits incurred through the plan for which they will receive full tax credit on future taxes owed to the State.

## Wisconsin

The Wisconsin Health Insurance Risk Sharing Plan was created in 1981 to provide health insurance for those unable to find adequate health insurance coverage due to their mental or physical condition.

### Eligibility

All Wisconsin residents who have been rejected by one health insurer or who have received notice of benefit reduction or a 50 percent or more premium increase are eligible for pool membership. There is no waiver of the 6-month waiting period for any condition diagnosed or treated in the 6 months preceding the plan. Effective April 21, 1988, Medicaid recipients can buy into the pool. This allows pool benefits to act as a supplementary coverage net to the primary assistance provided by Medicaid.

### Payments and Benefits

Two deductible plans are offered, one for $1,000 and the other for $500 under Medicare Part A. A 20-percent coinsurance payment is required for all services. There is a 150-percent maximum premium cap and a $500,000 maximum lifetime benefit. Stop loss/out-of-pocket expenses vary by plan but range from $500 (Medicare) to $2,000 for an individual, but is set at $4,000 for a family. Wisconsin has set aside revenue funds to subsidize premium payments and deductible costs. Policy holders with annual incomes below $16,000 can apply for subsidies to cover from 17 to 33 percent of premium costs and a reduces deductible of $500 to $900, depending on income bracket. Benefits include limited mental health services and the option to purchase durable medical equipment. The Medicare Supplement Plan is for those under 65 and receiving medical assistance.

### Administration

Mutual of Omaha is the plan administrator. The board is composed of nine members, including two participating insurers from nonprofit corporations, two other participating insurers, three public members (two of whom could qualify for coverage in the pool), a health policy council representative, and the Insurance Commissioner or a representative from the commissioner's office. All health care carriers, including health care service plans and health maintenance organizations authorized to issue insurance in the State, are required to be pool members (self-insurers can no longer be obligated to join). All pool members are assessed in proportion to their share of the State insurance market but can no longer credit assessment against the State premium tax. Effective January 1988, the State instigated a subsidy to policy holders in the form of $200,000 in tax relief from general revenues. This is used to moderate deductibles and cost sharing expenses for those in need of pool services yet unable to meet the pool costs. As of May, 1986, this plan assisted 1,964 individuals, an increase from the 309 participants in 1981.

## Catastrophic Health Insurance Plans

Unlike health insurance risk pools, plans established to offer coverage for those unable to procure adequate health care coverage elsewhere, catastrophic plans simply supplement already existing insurance plans. Catastrophic Health Insurance Plans (CHIPs) are operated by State Departments of Human Services and are generally used as a last resort source of funds to help pay for forbiddingly high medical bills. If medical costs financially drain a family to the point where their customary standard of living can no longer be maintained, a catastrophic plan can be purchased. After satisfying a deductible, the CHIP will pay the balance of expenses that private insurance will not cover. Deductibles are determined by a formula sensitive to the income of the applicant; a State may require a deductible of, for example, $2,500 plus 10 percent of the annual net income. Deductibles are usually set as per family rather than per capita requirements, although there have been exceptions. The costs are pro-rated in that those with no insurance pay much higher deductibles than those with private insurance policies, and Medicare recipients pay the least amount. The deductible screens out a majority of people, and of those remaining with high expenses, many are already covered by Medicare, Medicaid, and private sector health plans. Approximately 10 percent of the population has no coverage, and about half of the people with private insurance have catastrophic stop-loss coverage, so these people generally are the ones to take advantage of the catastrophic plans. Also, the non-poor elderly may have high enough expenses not covered by Medicare to qualify for CHIP membership. As for State expenses, when spreading the costs across the residents of the State, per capita costs hover around $2.00.

CHIP participation has been low; in 1986 the enrollment in Rhode Island was 624 and in Maine was 57. Although a few States have attempted catastrophic plans, only one, Rhode Island, has been successfully maintained. Rhode Island has the model CHIP in that it is the oldest (effective since 1975) and the sole plan able to continue service. Maine, Minnesota, and Alaska each had programs but lost appropriations and folded. The now defunct programs hope to be refunded but none received allocations for fiscal years 1988 and 1989. New Jersey passed a law in early 1988 to establish a Catastrophic Illness in Children Relief Fund. The program is based on the same principles of a CHIP yet is extremely limited in its service in that only children under 18 years of age are eligible for membership.

## Appendix C

# Medical Testing

Model Regulation Service — July 1987

## Medical/Lifestyle Questions and Underwriting Guidelines

## PROPOSED BULLETIN

(Effective Date)

SUBJECT: Medical/Lifestyle Questions on Applications and Underwriting Guidelines Affecting AIDS and ARC

(Recital of applicable authority if needed and purpose of bulletin. Issuance of bulletin is to assist insurers to formulate and design medical/lifestyle questions in applications for and underwriting standards affecting health and/or life insurance coverage in conformity with the fair standards adopted by the NAIC at its December 1986 meeting.)

I. General Propositions

A. No inquiry in an application for health or life insurance coverage, or in an investigation conducted by an insurer or an insurance support organization on its behalf in connection with an application for such coverage, shall be directed toward determining the applicant's sexual orientation.

B. Sexual orientation may not be used in the underwriting process or in the determination of insurability.

C. Insurance support organizations shall be directed by insurers not to investigate, directly or indirectly, the sexual orientation of an applicant or a beneficiary.

II. Medical Lifestyle Applications Questions and Underwriting Standards

A. No question shall be used which is designed to establish the sexual orientation of the applicant.

B. Questions relating to the applicant having or having been diagnosed as having AIDS or ARC are permissible if they are factual and designed to establish the existence of the condition.

For Example: Insurers should not ask "do you believe you may have . . .?", but rather "do you know or have reasons to know . . .?"

C. Questions relating to medical and other factual matters intending to reveal the possible existence of a medical condition are permissible if they are not used as a proxy to establish the sexual orientation of the applicant, and the applicant has been given an opportunity to provide an explanation for any affirmative answers given in the application.

For Example: "Have you had chronic cough, significant weight loss, chronic fatigue, diarrhea, enlarged glands, . . .?" These types of questions should be related to a finite period of time preceding completion of the application and should be specific. All of the questions above should provide the applicant the opportunity to give a detailed explanation.

D. Questions relating to the applicant's having or having been diagnosed as having or having been advised to seek treatment for a sexually transmitted disease are permissible.

E. Neither the marital status, the "living arrangements," the occupation, the gender, the medical history, the beneficiary designation, nor the zip code or other territorial classification of an applicant may be used to establish, or aid in establishing, the applicant's sexual orientation.

F. For purposes of rating an applicant for health and life insurance, an insurer may impose territorial rates, but only if the rates are based on sound actuarial principles or are related to actual or reasonably anticipated experience.

G. No adverse underwriting decision shall be made because medical records or a report from an insurance support organization shows that the applicant has demonstrated AIDS-related concerns by seeking counselling from health care professionals. This subsection does not apply to an applicant seeking treatment and/or diagnosis.

[Provision for States permitting testing]

H. Whenever an applicant is requested to take an AIDS-related test in connection with an application for insurance, the use of such a test must be revealed to the applicant and his or her written consent obtained. No adverse underwriting decision shall be made on the basis of such a positive AIDS-related test unless an established test protocol has been followed.

Note: "Established test protocol" means the protocol adopted in a particular state. At a minimum, it requires two positive ELISA tests. In some states, it also includes one positive Western blot. It is anticipated that new and more effective ADIS-related tests will be developed which might replace those currently in use.

I. Options to be considered by each state.

Alternative A. Insurers should not be permitted to ask an applicant whether he or she has tested positive on an AIDS-related blood test.

Alternative B. Insurers should be permitted to ask an applicant whether he or she has tested positive on an AIDS-related blood test.

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*Legislative History (all references are to the Proceedings of the NAIC).*

***1987 Proc. I 11, 19, 609, 655, 659-660 (adopted).***

## Appendix D

# OTA Survey Questionnaire

NOTE: The following pages reproduce the OTA survey questionnaire sent to the commercial health insurers. The questionnaire was modified slightly for the Blue Cross/Blue Shield plans and Health Maintenance Organizations to include proper terminology and reflect differences in rating and enrollment practices.

## CONGRESSIONAL OFFICE OF TECHNOLOGY ASSESSMENT

## DIAGNOSTIC AND PREDICTIVE MEDICAL TESTS PROJECT

## SURVEY OF HEALTH INSURANCE COMPANIES

### I. GENERAL INFORMATION

Company: ______________________________

Address: ______________________________

______________________________

Contact Person: ______________________

Title: ________________________________

Telephone: ____________________________

**PLEASE NOTE:** This survey focuses on three health insurance populations -- (1) *Individuals* who seek insurance independently and without any association with an employer or membership group of any kind. (2) *Individually underwritten groups*, i.e., those groups which are too small to qualify for experience rating and whose members must be individually underwritten. (3) *All other groups*, i.e., employee and other groups which do not require individual underwriting (except in the case of late entrants).

Please refer only to these three populations when responding to the questionnaire.

Conversions should be excluded from your responses. In addition, we prefer that you exclude Medigap insurance from your responses. If, because of reporting or other reasons, you must include Medigap policies, please check the box below:

☐ YES, Medigap policies and statistics are included in our responses to this survey.

**QUESTIONS:** Please call Jill Eden at the Office of Technology Assessment (telephone: 202-228-6590).

## II. UNDERWRITING PRACTICES

A. For each category of coverage, please estimate the proportion of health insurance applicants for whom:

| | Individual | Individually Underwritten Groups | All Other Groups |
|---|---|---|---|
| 1. An attending physician statement (APS) is required. | ______% | ______% | ______% |

** If an APS is required, which of the following factors trigger an APS request? (check all that apply)

☐ diagnosis or symptoms reported on application or examination
☐ age
☐ sex
☐ M.I.B., Inc.
☐ inspection report
☐ sexual orientation
☐ drug abuse history
☐ late group applicant
☐ geographic area
☐ other, please specify: ______________________

| | Individual | Individually Underwritten Groups | All Other Groups |
|---|---|---|---|
| 2. A physical exam is conducted. | ______% | ______% | ______% |

** If a physical exam is conducted, which of the following factors trigger a request for a physical? (check all that apply)

☐ diagnosis or symptoms reported on application
☐ APS findings
☐ age
☐ sex
☐ MIB, Inc.
☐ inspection report
☐ sexual orientation
☐ drug abuse history
☐ late group applicant
☐ geographic area
☐ other, please specify: ______________________

| | Individual | Individually Underwritten Groups | All Other Groups |
|---|---|---|---|
| 3. Blood or urine screens are performed. | _______% | _______% | _______% |

** If screening is performed, please indicate the names of the tests included in the screen: (Or attach a list)

| Blood | Urine |
|---|---|
| ____________________ | ____________________ |
| ____________________ | ____________________ |
| ____________________ | ____________________ |
| ____________________ | ____________________ |
| ____________________ | ____________________ |
| ____________________ | ____________________ |
| ____________________ | ____________________ |
| ____________________ | ____________________ |
| ____________________ | ____________________ |

| | Individual | Individually Underwritten Groups | All Other Groups |
|---|---|---|---|
| 4. A financial or personal investigation is conducted (e.g., motor vehicle or credit checks). | _______% | _______% | _______% |

B. For individually underwritten applicants, please indicate the importance of each of the following factors in determining insurability: (Note the response definitions below. For each factor, place a check in only one of the columns.)

| | Very Important | Important | Unimportant | Never Used |
|---|---|---|---|---|
| 1. age | ____ | ____ | ____ | ____ |
| 2. type of occupation | ____ | ____ | ____ | ____ |
| 3. avocation (e.g., skiing or skydiving) | ____ | ____ | ____ | ____ |
| 4. financial status (i.e., income or credit worthiness) | ____ | ____ | ____ | ____ |
| 5. health endangering personal habits (e.g., alcohol or drug abuse) | ____ | ____ | ____ | ____ |
| 6. health enhancing personal behavior (e.g., premium credits for non-smokers) | ____ | ____ | ____ | ____ |
| 7. illegal or unethical behavior (e.g., criminal or questionable business practices) | ____ | ____ | ____ | ____ |
| 8. place of residence | ____ | ____ | ____ | ____ |
| 9. sexual orientation | ____ | ____ | ____ | ____ |
| 10. other, specify: ______________ | ____ | ____ | ____ | ____ |

PLEASE NOTE THESE DEFINITIONS:

Very Important - Critical to underwriting process; can affect acceptance/rejection.

Important - Always considered but will never by itself affect acceptance/rejection. It may, however, influence coverage limits (e.g., exclusions or waiting period) and/or premium.

Unimportant - Rarely affects acceptance/rejection, coverage limits, or premium -- unless in conjunction with other more important factors.

Never Used - Never considered.

C. Please answer the following questions regarding your company's AIDS policies:

| | Individual | Individually Underwritten Group | All Other Groups |
|---|---|---|---|
| 1. Do you attempt to identify applicants who have been exposed to the AIDS virus? (check one for each category) | | | |
| - yes | ☐ | ☐ | ☐ |
| - no, but plan to | ☐ | ☐ | ☐ |
| - no, and no plans to | ☐ | ☐ | ☐ |
| - other, specify: ________________ | ☐ | ☐ | ☐ |

** If yes (or "no, but plan to"), please indicate the following: (All others go to question #2, next page)

a. Screening method (check all that apply):

| | Individual | Individually Underwritten Group | All Other Groups |
|---|---|---|---|
| - question(s) on application | ☐ | ☐ | ☐ |
| - attending physician statement | ☐ | ☐ | ☐ |
| - ELISA only | ☐ | ☐ | ☐ |
| - ELISA and Western blot (if positive ELISA) | ☐ | ☐ | ☐ |
| - T-cell subset study | ☐ | ☐ | ☐ |
| - other blood tests, specify: ________________ ________________ | ☐ | ☐ | ☐ |

|  | Individual | Individually Underwritten Groups | All Other Groups |
|---|---|---|---|
| b. Which applicants are (or will be) required to have an AIDS blood test? |  |  |  |
| - All applicants | ☐ | ☐ | ☐ |
| - Applicants at high risk for AIDS | ☐ | ☐ | ☐ |
| c. If only applicants at high risk for AIDS are tested, who is selected? (check all that apply) |  |  |  |
| - all males | ☐ | ☐ | ☐ |
| - applicants with history of sexually transmitted disease | ☐ | ☐ | ☐ |
| - hemophiliacs | ☐ | ☐ | ☐ |
| - applicants with history of receiving blood transfusions | ☐ | ☐ | ☐ |
| - drug abusers | ☐ | ☐ | ☐ |
| - other, specify: ______________ | ☐ | ☐ | ☐ |
| 2. How many of your insureds have you reimbursed for AIDS-related claims? | ______ | ______ | ______ |
| - please specify related time period: | ______ | ______ | ______ |
| 3. If available, please indicate your company's projected AIDS-related claims costs for 1987. | $______ | $______ | $______ |
| 4. If your company has had AIDS-related claims, what percent of the individuals with AIDS have been found to have a preexisting condition for AIDS? (check one for each category) |  |  |  |
| - 0 percent | ☐ | ☐ | ☐ |
| - 1 to 9 percent | ☐ | ☐ | ☐ |
| - 10 to 50 percent | ☐ | ☐ | ☐ |
| - greater than 50 percent | ☐ | ☐ | ☐ |

5. Does your company plan to do any of the following, in response to the financial impact of AIDS (please check all that apply):

- Withdraw from the individual health market altogether ☐
- Exclude AIDS and/or sexually transmitted diseases from individual health coverage ☐
- Reduce company exposure in the individual and small group health markets (e.g., by introducing more restrictive underwriting guidelines). ☐
- Expand HIV or other testing of applicants ☐
- Other, specify: ____________________ ☐

## III. INDIVIDUAL AND SMALL GROUP STATISTICS

| | Individual Policies | Individually Underwritten Groups |
|---|---|---|
| A. Average number of applications per year | ______ | ______ |
| B. Please indicate proportion of individuals that are: (numbers should total 100%) | | |
| - accepted at standard rates | ______ % | ______ % |
| - covered with an exclusion waiver only | ______ % | ______ % |
| - covered with a rated premium only | ______ % | ______ % |
| - covered with an exclusion waiver and rated premium | ______ % | ______ % |
| - declined | ______ % | ______ % |
| TOTAL | 100 % | 100 % |

C. If members of individually underwritten groups are not rated, ridered, or declined on an individual basis, what proportion of the groups, as a whole, are:

- accepted with a rated premium ______ %
- declined ______ %

D. This question concerns individually underwritten policies only. Read the list below and place a check in column 2 next to the ten diagnoses which account for the largest proportion of your claims costs. In column 3, please estimate the proportion of total costs that each of the top ten diagnoses represents. In column 4, rank the ten diagnoses (i.e., 1 - 10) in order of cost.

| DIAGNOSIS | (1) ICD9-CM CODES | (2) TOP TEN | (3) ESTIMATED % OF TOTAL COST | (4) RANK |
|---|---|---|---|---|
| 1. AIDS and related conditions* | See note below. | [ ] | ______% | ____ |
| 2. Diseases of the blood and blood-forming organs and immunity (excluding AIDS and related conditions) | 280-289 | [ ] | ______% | ____ |
| 3. Circulatory system (please specify below) | | | | |
| - Essential hypertension | 401 | [ ] | ______% | ____ |
| - Heart disease | 391-392.0, 393-398, 402, 404, 410-416, 420-429 | [ ] | ______% | ____ |
| - Cerebrovascular disease | 430-438 | [ ] | ______% | ____ |
| - Other circulatory system disorders | 390, 392.9,399-400, 403, 405-409,417-419, 430-459,785 | [ ] | ______% | ____ |
| 4. Congenital abnormalities/conditions of perinatal | 740-779, V30-V39 | [ ] | ______% | ____ |
| 5. Diseases of the digestive system | 520-569, 787 | [ ] | ______% | ____ |
| 6. Diseases of the ear, nose and throat | 380-389, 460-464, 784 | [ ] | ______% | ____ |

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*Note: Please include any insured diagnosed with AIDS, ARC, or any opportunistic infection thought to be AIDS-related.

| DIAGNOSIS | (1) ICD9-CM CODES | (2) TOP TEN | (3) ESTIMATED % OF TOTAL COST | (4) RANK |
|---|---|---|---|---|
| 7. Endocrine, nutritional, and metabolic diseases | | | | |
| - Diabetes mellitus | 250 | [ ] | ______% | ____ |
| - Other | 240-249,251-279,783 | [ ] | ______% | ____ |
| 8. Diseases of the eye | 360-379 | [ ] | ______% | ____ |
| 9. Diseases of the female reproductive system | 614-629 | [ ] | ______% | ____ |
| 10. Diseases of the liver, gallbladder and pancreas | 570-579, 789 | [ ] | ______% | ____ |
| 11. Infectious and parisitic diseases | 001-139 | [ ] | ______% | ____ |
| 12. Injury, poisoning, and toxic effects of drugs | 800-939, 940-999, E800-E998 | [ ] | ______% | ____ |
| 13. Diseases of the kidney and urinary tract | 580 -599, 788 | [ ] | ______% | ____ |
| 14. Diseases of the male reproductive system | 600-608 | [ ] | ______% | ____ |
| 15. Mental disorders | 290, 293-302, 306-319 | [ ] | ______% | ____ |
| 16. Diseases of the musculoskeletal system and connective tissue | 710-739 | [ ] | ______% | ____ |
| 17. Neoplasms (please specify below if possible) | | | | |
| - Malignant neoplasm of trachea, bronchus, and lung | 162, 197.0, 197.3 | [ ] | ______% | ____ |
| - Malignant neoplasm of breast | 174 - 175, 198.81 | [ ] | ______% | ____ |
| - Other neoplasms | 140-161, 163-174, 176-196, 197.2, 197.4-198.8, 199-239 | [ ] | ______% | ____ |

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| DIAGNOSIS | (1) ICD9-CM CODES | (2) TOP TEN | (3) ESTIMATED % OF TOTAL COST | (4) RANK |
|---|---|---|---|---|
| 18. Diseases of the nervous system | 320-359, 780-781 | [ ] | ________% | ____ |
| 19. Pregnancy, childbirth, and the puerperium | 630-676 | [ ] | ________% | ____ |
| 20. Diseases of the respiratory system | 465-519 | [ ] | ________% | ____ |
| 21. Diseases of the skin, subcutaneous tissue, and breast | 680-709, 610-611, 782 | [ ] | ________% | ____ |
| 22. Substance use (including alcohol) and induced organic disorders | 291-292, 303-305 | [ ] | ________% | ____ |

## IV. MATERIAL REQUESTS

Please attach a sample of the following (for individually underwritten applicants only):

1. individual application

2. individual policies or brochures

3. attending physician statement (if used)

4. lab report form (if used)

5. list of uninsurable medical conditions, i.e., diagnoses for which coverage will not be offered (If a complete list is unavailable, please list the fifteen most common uninsurable conditions).

6. list of medical conditions requiring a temporary or permanent exclusion waiver (if used) (If a complete list is unavailable, please list the fifteen most common conditions).

7. list of medical conditions requiring a rated premium (if used) (If a complete list is unavailable, please list the fifteen most common conditions).

## V. COMMENTS

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**Please return survey in the enclosed, stamped envelope to:** Jill Eden, Office of Technology Assessment, Health Program, United States Congress, Washington, D.C. 20510-8025.

## Appendix E

# Acknowledgments

The development of this report has benefited from the advice and review of a number of people in addition to the advisory panel. OTA staff would like to express its appreciation of the following people for their valuable guidance.

Bob Arnold
University of Pennsylvania
Philadelphia, PA

J. Robert Beck
Dartmouth-Hitchcock Medical Center
Hanover, NH

Jan L. Breslow
The Rockefeller University
New York, NY

T. Thomas Casky
Institute for Molecular Genetics
Baylor College of Medicine
Houston, TX

Charles Eby
Health Insurance Association of America
Washington, DC

Paul S. Frame
Tri-County Family Medicine
Cohocton, NY

Marsha Gold
Group Health Association of America
Washington, DC

Neil A. Holtzman
The Johns Hopkins University School of Medicine
Baltimore, MD

Mark Joffey
Group Health Association of America
Washington, DC

Diana Jost
Blue Cross and Blue Shield Association of America
Washington, DC

Mary Nell Lehnhard
Blue Cross and Blue Shield Association of America
Washington, DC

David Llewellyn
Health Insurance Association of America
Washington, DC

Sue Palsbo
Group Health Association of America
Washington, DC

Theodore Reich
Department of Psychiatry
Jewish Hospital of St. Louis
St. Louis, MO

Bill Roberts
Home Office Reference Laboratories
Shawnee Mission, KS

Robin Wagner
Blue Cross and Blue Shield Association of America
Washington, DC

Kenneth R. Warren
National Institute on Alcohol Abuse and Alcoholism
Rockville, MD

Steve White
Metropolitan Life Insurance Co.
New York, NY

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